relationships with entities that they placed under contract to perform certain functions that otherwise would be the responsibility of the organization to perform including management and provision of services. This section therefore addresses these relationships and establishes requirements that the M+C organizations must adhere to in order to provide HCFA assurances that the M+C organization will be accountable for all contract requirements.

Specifically, this section gives HHS, the Comptroller General or their designee, the authority to audit, evaluate and/or inspect documents, papers, records of all of the organizations mentioned in § 422.502(i); and to obtain information from the M+C organization and other entities described here, six years following the close of a contract or audit. Paragraph (i)(3) of § 422.502 describes provisions that must be included in contracts and other written arrangements between M+C organizations and other entities described in this section.

- Section 422.502(j), which is derived from section 1857(e), states that the contract will contain other terms and conditions consistent with this part as HCFA may find necessary and appropriate.
- Under § 422.502(k), we require that all M+C contracts be severable as discussed previously.

Finally, pursuant to our authority in section 1856(b)(1) to establish standards under Part C by regulation, we are requiring in paragraphs (l) and (m) that an M+C organization request payment on document that certify the accuracy and completeness of relevant data as a condition for receiving its capitation payment and, in the case of the ACR, for retaining the portion of capitation payment associated with the ACR amount (rather than providing additional benefits). Section 422.502(b) also states that the M+C organization's CEO or CFO certify the accuracy of encounter data, and, in instances when encounter data are generated by a related entity, contractor, or subcontractor, such entity likewise certifies the accuracy of the encounter data.

In all of these cases, when an M+C organization submits the data in question to HCFA, we believe that it is making a ''claim'' for capitation payment in the amount dictated by the data submitted, or in the case of the ACR submission, a ''claim'' to retain the portion of the capitation payment that is under the ACR amount, rather than providing additional benefits. We believe it is important that when an M+C organization is claiming payment (or the right to retain payment) in a particular amount based upon information it is submitting to HCFA, it should be willing to certify the accuracy of this information. We believe that these certifications will help ensure accurate data submissions, and assist HCFA and the Office of Inspector General in anti-fraud activities.

4. Effective Date and Term of Contract (§ 422.504)

Section 1857(c) provides that each contract under section 1857 will be for a term of at least 1 year, as determined by the Secretary. This section also provides that the effective date and term of the contract will be specified in the contract, except that in no case will a contract under this section that provides for coverage under an M+C MSA plan be effective before January 1999 with respect to such coverage. Based on these provisions, § 422.504(b) of this rule provides that beginning in 2002, contracts will be for a period of 12 months beginning on January 1 and ending on December 31. We include an exception at § 422.504(d) which indicates that prior to January 1, 2002, HCFA may at its discretion approve contracts for periods longer than 12 months, that begin on a date other than January 1.

HCFA has decided not to exercise the discretion provided in section 1857(a)(1) to make contracts automatically renewable (section 1857(a)(1) provides that contracts ''may'' be automatically renewable from term to term.) Instead, we specify at § 422.504(c) that the contract may be renewed annually only if HCFA affirmatively authorizes a renewal, and the M+C organization has not given HCFA a notice of nonrenewal. We believe that this approach is consistent with HCFA's role as a prudent purchaser and is in the best interest of the tax payer, the Medicare beneficiary and the Medicare program.

Under the current 1876 risk contract program, HCFA receives applications on a continuous basis and also awards contracts on a continuous basis as soon as the review process is complete, and a decision for approval has been reached. We have decided to maintain this process for the next few years under the M+C program. The BBA, however, provides a framework that has encouraged us to consider changing this in the future. The requirements for a coordinated open enrollment policy and printed plan comparison charts and the advent of the lock-in periods starting in 2002 suggests that HCFA move toward a policy of establishing a cutoff date for awarding contracts annually. This cutoff date would be timed to ensure that all new plans are included in the printed plan comparison charts. If we established a cutoff phase, HCFA would implement this change to the application and award processes in the year 2001 in time for the first year of the lock-in. We invite comments on this issue.

5. Nonrenewal of Contract (§ 422.506)

Section 422.506(a) discusses the process that an M+C organization must follow if it decides not to renew its contract. If the M+C organization does not want to renew its contract, it must notify HCFA in writing by May 1 of the year preceding the year that the M+C organization intends to no longer contract with HCFA. In addition, the M+C organization must notify each Medicare enrollee by mail at least 90 days before the effective date of the nonrenewal. It must also notify the general public at least 90 days before the end of the current calendar year by publishing a notice in one or more of the newspapers of general circulation located in the M+C's geographic area.

We also provide that HCFA may accept a nonrenewal notice of an M+C organization's decision not to renew its contract submitted after May 1 if the M+C organization complies with the requirements concerning enrollee and public notification and acceptance would not otherwise jeopardize the effective and efficient administration of the Medicare program. The May 1 deadline is timed to coincide with the ACR submission and internal HCFA timelines that require the timely submission of information necessary for developing annual health fair/open enrollment materials that will be made available to new and already-enrolled Medicare beneficiaries. We believe that the conference committee reports make it clear that the Congress intends for Medicare beneficiaries to make informed choice based on accurate, comparative M+C plan information. The Conferees further make it clear that the Secretary must take all steps necessary to ensure that all Medicare beneficiaries are provided the information needed to make informed choices about health coverage. We assert that the date-specific deadlines by which an M+C organization must notify HCFA of its decision not to renew its contract is a necessary step that promotes and represents the best intent of the law.

Section 1857(c)(4) provides that the Secretary cannot enter into an M+C contract with an M+C organization if, within the preceding five years, that organization has had an M+C contract

that was ''terminated at the request of the organization,'' except ''in circumstances that warrant special consideration, as determined by the Secretary.'' While Congress used the word ''terminated'' rather than ''nonrenewed,'' the only way that a contract could end solely ''at the request of the organization'' would be as the result of a notice of nonrenewal of the contract. In the case of a termination by mutual consent, discussed below, this only occurs if *HCFA* agrees that a termination of the contract is in the best interests of beneficiaries. Even in the case of a termination by the M+C organization under § 422.512 (discussed below), an organization does not have the right simply to ''request'' termination of the contract. Rather, it must show HCFA noncompliance with HCFA's obligations. This has never happened under the Part 417 counterpart of this authority for an organization to terminate its contract (§ 417.494(c)). Thus, we have always interpreted similar language in section 1876 to apply when an organization *nonrenews* its contract. We therefore make this interpretation explicit in § 422.506(a)(4).

HCFA decision not to authorize renewal. In accordance with § 422.506, contracts are renewed annually only if (1) HCFA informs the M+C organization that it authorizes a renewal and (2) the M+C organization has not provided HCFA with a nonrenewal notice. Section 422.506(b)(1) provides that HCFA may decline to authorize a renewal of a contract for any of the following reasons:

- The M+C organization has not fully implemented or shown discernable progress in implementing quality improvement projects;
- The M+C organization demonstrates insufficient enrollment growth. As participation in the M+C program grows it is inevitable that some contracting entities will not enroll sufficient numbers of Medicare beneficiaries to justify the administrative costs associated with regulating meet the applicable minimum enrollment requirements at § 522.514.
- For any of the reasons listed in § 422.510(a) which would also permit HCFA to terminate the contract.
- The M+C organization has committed any of the acts in § 422.752(a) which would support the imposition of intermediate sanctions or civil money penalties under Subpart O.

We believe that these aforementioned reasons for not authorizing renewal of a contract are consistent with HCFA's intent to fulfill its role as a prudent purchaser of health care services.

Section 422.506(b)(2) provides that if HCFA decides not to authorize the renewal of a contract, HCFA gives written notice to—

- The M+C organization by mail by May 1 of the current calendar year;
- The M+C organization's enrollees at least 90 days before the end of the current calendar year; and
- The general public, by publishing a notice in one or more newspapers of general circulation in each community or county located in the M+C organization's service area, at least 90 days before the end of the current calendar year.

Section 422.506(b)(3) provides that HCFA give the M+C organization written notice of its right to appeal the nonrenewal decision in accordance with subpart N.

6. Modification or Termination of a Contract by Mutual Consent (§ 422.508)

We provide guidance at § 422.508(a) that allows for contract termination by mutual consent. If a contract is terminated by mutual consent, except as provided in the § 422.508(b), the M+C organization must provide notice to its Medicare enrollees and the general public as provided in § 422.512(b) (2), and (3). If the contract terminated by mutual consent is replaced on the following day by a new M+C contract, the notice specified above does not need to be provided.

We have developed a mutual consent termination policy because we believe that there are circumstances under which an M+C organization may agree to a mutual termination by consent. This policy gives HCFA the option to offer this alternative to affected M+C organizations. Further, HCFA may decide that it is in the best interests of tax payers, Medicare beneficiaries and the Medicare program to agree to let an M+C organization terminate its contract midyear. Finally, we believe this policy accommodates M+C organizations that may wish to terminate their contract by mutual consent at the end of a calendar year and enter into a new 12 month contract year on January 1 during the years prior to 2002. We invite comment on this proposed policy.

In § 422.508, with some modifications, we have retained the provision for contract modification or termination by mutual consent that applies to contracts under section 1876. As under § 417.494(a), contracts may be modified or terminated at any time by written mutual consent. The two changes we have made are that (1) we have changed the obligation to provide enrollees and the public with notice of a termination to conform to the 60-day notice requirement in § 422.512(b) (2) and (3) (which retained the enrollee notice requirement in § 417.484(c)(2)); and (2) we have provided for an exception to the notice requirement for cases in which a contract being terminated by mutual consent is being replaced by a new contract on the day the termination becomes effective. We continue to require that M+C organizations notify their Medicare beneficiary enrollees of any changes that may occur pursuant to a contract modification by mutual consent within timeframes specified by HCFA.

7. Termination of a Contract by HCFA (§ 422.510)

Section 1857(c)(2) provides that the Secretary may at any time terminate an M+C organization contract if the Secretary determines that the M+C organization—

- Failed substantially to carry out the contract;
- Is carrying out the contract in a manner inconsistent with the efficient and effective administrative of Medicare Part C; or
- No longer substantially meet the applicable conditions of Medicare Part C.

In addition to repeating the above statutory language, we are implementing this language by identifying specific circumstances that we believe constitute examples of an M+C organization substantially failing to carry out either its contract, or carrying out its contract in a manner that is inconsistent with the effective and efficient administration. Specifically, we have identified the following circumstances: The M+C organization commits or participates in fraudulent or abusive activities affecting the Medicare program; the M+C organization substantially fails to comply with requirements in Subpart M relating to grievances and appeals; the M+C organization fails to provide HCFA with valid encounter data as required under § 422.257; the M+C organization fails to implement an acceptable quality assessment and performance improvement program as required under Subpart D; the M+C organization substantially fails to comply with the prompt payment requirements in § 422.520; the M+C organization substantially fails to comply with the service access requirements in § 422.112 or § 422.114; the M+C organization fails to comply with the requirements of § 422.208 regarding physician incentive plans.

Section 1857(h)(2)provides authority for the Secretary to immediately terminate a contract with an M+C organization in instances where the

Secretary determines that a delay in termination resulting from compliance with the procedures in section 1857(h)(1) discussed below would pose an imminent and serious risk to the health of enrolled Medicare beneficiaries.

We have implemented this authority as follows. First, § 422.510(a)(5) provides for termination when an M+C organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or when the organization otherwise fails to make services available to the extent that such a risk to health exists. Second, § 422.510(b)(2) provides that a termination based on § 422.510(a)(5) takes effect immediately. Third § 422.510(c) provides that the opportunity for corrective action does not apply to a termination based upon § 422.510(a)(5). And fourth, subpart N of part 422 provides that in the case of a termination based on § 422.510(a)(5), a hearing is not provided until after the termination takes effect.

Section 1857(h)(1) specifies procedures that must be followed before a termination by HCFA can take effect (unless the exception for an imminent and serious risk to health applies, as discussed above). We specify these requirements at § 422.50(b)(1). Section 1857(h)(1)(A) requires that the M+C organization be provided with a ''reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies'' that were the basis for a decision that grounds for termination existed under section 1857(c)(2). Section 422.510(c) provides for such a corrective action opportunity, consistent with time frames specified in Subpart N, except in cases in which the termination is based upon § 422.510(a)(5), and the ''imminent and serious'' risk to health exception in section 1857(h)(2) applies.

Section 1857(h)(1)(B) requires that the Secretary provide the M+C organization with ''reasonable notice and opportunity for hearing,'' including ''the right to appeal an initial decision * * * *before* terminating the contract.'' (Emphasis added.) Section 422.510(d) implements this provision by requiring that a notice of appeal rights under Subpart N be provided when a termination notice is sent to an M+C organization. This notice would specify that the termination would not be effective until after the hearing and appeal, except in the case of a termination under § 422.510(a)(5).

Also, in instances where it is necessary for HCFA to immediately terminate its contract with an M+C organization for violations prescribed in § 422.510(a)(5), we specify in § 422.510(b)(2) that if a termination notice is sent and takes effect in the middle of the month, HCFA has the right to recover a prorated share of its payment made to the M+C organization at the beginning of the month following notice of said termination.

8. Termination of a Contract by the M+C Organization (§ 422.512)

Paragraph (a) of § 422.512 provides that the M+C organization may terminate the contract if HCFA has failed substantially to carry out the terms of the contract. The paragraph (b) through (d) establishes requirements for giving notice, specifies when the termination is effective, and establishes when HCFA's liability for payment to the M+C organization ends. Paragraph (e) states that organizations that terminate their contract with HCFA cannot enter into an agreement with the Secretary for five years unless there are circumstances that warrant special consideration.

9. Minimum Enrollment Requirements (§ 422.514)

The newly-created section 1857(b) of the Act specifies that HCFA may not enter into a contract with an M+C organization unless the organization has at least 5,000 enrollees (or 1,500 if it is a PSO), or at least 1,500 enrollees (or 500 if it is a PSO) if the organization primarily serves individuals residing outside of urbanized areas. We specify these requirements in § 422.514(a).

Section 1857(b) refers to individuals ''who are receiving health benefits through the organization.'' We considered interpreting receiving health ''benefits'' to mean more than simply receiving health *services.* A hospital or doctor can furnish health services on a fee-for-service basis, or an organization can *administer* health benefits offered by an employer without actually providing ''benefits'' in the form of covered costs. We also recognize that some new organizations, both federally waivered PSOs and new state licensed entities, will apply to enter the M+C program. Thus, such an interpretation would allow some new entities to achieve the minimum enrollment requirement without having any or very little enrollment.

The minimum enrollment requirement is an indicator that the organization applying for an M+C contract can handle risk and capitated payments and also is able to effectively manage a health care delivery system including the enrollment and disenrollment of beneficiaries and the timely payment of claims, provide quality assurance, and have systems to handle grievances and appeals. While having experience with risk based payments indicates the organization can handle risk, it does not provide any assurance that the organization can manage all the contractual requirements of an M+C organization.

We realize that through the waiver process for federally waivered PSOs and the application process for all new entities we require reasonable assurance that the organization will be able to manage their contract. We do not want to add an additional barrier to entry for those organizations that have gone through the waiver process or state licensure but are still start-up organizations.

We have decided to require that the minimum enrollment requirement can only be met counting enrollees in the particular organization. This will show the organization can handle risk and manage their system.

Section 1857(b)(2) contains the statement that the term ''covered lives'' should be substituted for ''individuals'' in applying the minimum enrollment rule to MSA plans. As such, we will count covered lives for MSAs for purposes of meeting the minimum enrollment requirements.

As stated earlier, section 1857(b)(3) allows M+C organizations to request a waiver of minimum enrollment requirements during the first 3 contract years. Therefore, under § 422.514(b) HCFA may waive the minimum enrollment requirement for 1 year to those organization that need a waiver provided such organizations satisfactorily demonstrate: prior experience with risk-based payment arrangements; the ability to bear financial risk under the M+C contract; and marketing and enrollment activities necessary to meet enrollment requirements specified at § 422.514 (a)(1) and (a)(2). Both HCFA actuaries and the National Association of Insurance Commissioners recommend against entering into an contract with a applicant who does not project reaching 500 members within a short timeframe. HCFA will monitor closely the progress of organizations in meeting at least this goal during the first contract year.

If the organization does not meet the applicable minimum enrollment requirement by the end of its first year of operation we may waive the requirements for an additional year if the organization meets the requirement specified in § 422.514(b)(2):

- Requests an additional minimum enrollment waiver at least 120 days before the end of the year;
- Continues to demonstrate an ability to meet its contractual obligations and bear financial risk; and,
- Demonstrates an acceptable marketing and enrollment process. The organization's enrollment projections for the second year of the waiver will become its enrollment standard.

In paragraph § 422.514(b)(3) we state that we will only approve a third and final waiver year if the organization has achieved the transitional enrollment standard that the organization projected in their marketing and enrollment plan required to receive a waiver for their second year.

Finally, if an organization does not achieve the minimum enrollment requirement and is not operating with a minimum enrollment waiver, HCFA may elect not to renew the M+C organization's contract, we specify this at § 422.514(c).

10. Reporting Requirements (§ 422.516)

This M+C regulation contains a number of sections that specify information requirements for M+C organizations. This information is to be provided from organizations to HCFA (see §§ 422.64, 422.502, and 422.512), from HCFA to beneficiaries (see § 422.64), and from the organizations to the beneficiaries (see §§ 422.80 and 422.110).

The following listing summarizes all the information required to be disclosed either to HCFA, to beneficiaries, or to both:

- Benefits
- Premiums
- Service area
- Quality and Performance: Outcomes, HEDIS, Disenrollment, satisfaction
- Supplemental benefits
- Access: Number, mix, and distribution of providers
- Out of area coverage
- Emergency care coverage
- Supplemental premiums
- Prior authorization rules
- Grievances and appeals procedures and data
- Quality assurance program
- Utilization controls
- Compensation methods
- Financial reports
- Encounter data
- Claims
- Enrollment

These represent an extensive amount of information to be disclosed both to HCFA and to beneficiaries. M+C organizations need to be particularly aware of the many requirements to disclose information to beneficiaries as seen in §§ 422.80 and 422.110. They will have to develop management information systems that meet these disclosure requirements. As it is, these sections specify the basic requirements as to information to be disclosed. HCFA will provide more detailed policy guidance on specific contents required for each of these data elements. These additional requirements will be developed with input from the public, such as plans, consumer groups, etc.

M+C organizations also need to take into consideration in the development of these management information systems, that they will soon have to meet the requirements of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996. This act will result in regulations for data standards that effect all components of the health care system. The act will specify standards for the following types of transactions: claims, enrollment and disenrollment, eligibility, payments and remittances, premiums, first report of injury, claim status, referral, providers, patient identifiers, health plan identifiers, and code sets. The organizations will also need to be in compliance with year 2000 changes.

Furthermore, M+C organizations will need to address the confidentiality and privacy provisions of these regulations and related regulations, meet the validation requirements associated with several of the data sets incorporated into this regulation, e.g, encounter data will need to be validated, and be capable of electronically transmitting this information to HCFA in the future, when such is so specified.

Section 1857(d) contains several provisions involving the financial records and financial status of M+C organizations. As discussed above, paragraphs (1) and (2) of section 1857(d) provide for auditing and inspection of M+C organizations' financial records. The paragraph (4) in section 1857(d) specifically requires that organizations ''in accordance with regulations of the Secretary, report to the Secretary financial information,'' which ''shall include'' such information as the Secretary may require demonstrating that the organization has a fiscally sound operation. Under our authority at section 1856(b)(2) to adopt section 1876 standards, we have decided to implement this authority in part by requiring that M+C organizations comply with financial reporting requirements currently set forth in § 417.126. These requirements are set forth in § 422.516(a) and (b). We believe that requirements specified in section 1857(d)(1), which require HCFA to conduct annual audits of the financial records of M+C organizations, compel M+C organizations to provide all required information described at § 422.516(a) and (b). Included in these requirements are—

- Requirement that M+C organizations develop and maintain a system for reporting information to HCFA, its enrollees and the general public, information described elsewhere in the regulation.
- A requirement that each M+C organization report to HCFA a description of significant business transactions.
- A requirement that each M+C organization submit combined financial statements to HCFA on a timely basis, as defined by HCFA.
- A requirement that for any employees' health benefits plan that includes an M+C organization in its offering, the M+C organization must furnish, upon request, the information the organization needs to fulfill its reporting and disclosure obligations (with respect to the particular M+C organization) under the Employee Retirement Income Security Act of 1974 (ERISA).
- A requirement that the organization notify HCFA regarding any loans or other special financial arrangements.
- A requirement that each M+C organization must make financial information available to enrollees upon request.

11. Prompt Payment Requirements (§ 422.520)

Under § 422.520, contracts with M+C organizations must specify that the M+C organization agrees to provide prompt payment of claims that have been submitted by providers for services and supplies rendered to Medicare enrollees when these services and supplies are not furnished by an organization-contracted provider. While this requirement closely follows requirements already in place for section 1876 contractors, (including provisions pertaining to interest to be paid if timely payment is not made), section 1857(f) extends similar prompt payment requirements to claims submitted by Medicare beneficiaries enrolled in M+C private fee-for-service plans. Section 422.520(a) contains this new section 1857(f) requirement, as well as the requirement that applies to non-contracting providers. Further, pursuant to our authority under section 1856(b)(1) to establish standards under Part C, we require organizations to act upon (either approve or deny, not

necessarily pay) all claims within 60 calendar days from the date of request. These claims include the remaining 5 percent of the clean claims not paid within 30 days as well as all other claims.

In addition, pursuant to our authority in section 1856(b)(1) to establish standards under Part C, we are requiring in § 422.520(b) that contracts or other written agreements between M+C organizations and providers and suppliers contain a ''prompt payment'' provision, the terms of which are developed and agreed to by the M+C organization and the relevant provider.

Section 1857(f)(2) also contains another new provision that specifies that if the Secretary determines that the organization fails to make payments promptly to non-contracting providers and suppliers as required under section 1857(f)(1) (and § 422.520(a)), the Secretary may provide for direct payments to affected providers and suppliers. We articulate these requirements in § 422.520(c).

Special Rules for RFB Societies

Enrollment restriction rules may be imposed by religious fraternal benefit society M+C organizations, provided the restriction of enrollment is consistent with the requirements identified in section 1859(e) of the Act. The RFB M+C organizations must still meet the requirements for financial solvency. Moreover, the Secretary may adjust the M+C organization's payment to account for the unique actuarial characteristics of the individuals enrolled in the RFB M+C organization. We specify these requirements in § 422.250(a).

L. Effect of Change of Ownership or Leasing of Facilities During Term of Contract

This interim final rule applies to M+C organizations the provisions concerning the effect of change of ownership or leasing facilities during the term of the contract that are currently set forth with regard to HMOs and CMPs in subpart M of part 417 to M+C organizations. This is accomplished by designating §§ 417.520 through 417.523 as §§ 422.550 through 422.533 in a new subpart L in part 422 and making certain nomenclature changes. (A cross-reference to subpart L of part 422 is included in subpart M of part 417 in order that these provision may continue to apply to Medicare contracts with HMOs and CMPs under section 1876.) We also revise redesignated § 422.550 (formerly § 417.520) to add that an M+C organization that has Medicare contract in effect and is considering or negotiating a change in ownership must provide to HCFA updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization. We also add this requirement to redesignated § 422.552 (formerly § 417.522), which contains requirements relating to novation agreements.

M. Subpart M—Grievances, Organization Determinations, and Appeals (§§ 422.560 Through 622)

1. Introduction

Subpart M of part 422 implements sections 1852(f) and (g), which set forth the procedures M+C organizations must follow with regard to grievances, organization determinations, and reconsiderations and other appeals. Under section 1852(f), an M+C organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any other entity or individual through which the organization provides health care services) and enrollees in its M+C plans. Section 1852(g) addresses the procedural requirements concerning coverage (''organization'') determinations and reconsiderations and other appeals. As discussed in detail below, only disputes concerning ''organization determinations'' are subject to the reconsideration and other appeal requirements under section 1852(g). In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. All other disputes are subject to the grievance requirements under section 1852(f). For purposes of this regulation, a reconsideration consists of a review of an adverse organization determination (a decision that is unfavorable to the M+C enrollee, in whole or in part) by either the M+C organization itself or an independent review entity. We use the term ''appeal'' to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Departmental Appeals Board (DAB) and judicial review.

For the grievance, organization determination, and appeal requirements, an M+C organization must establish procedures that satisfy these requirements with respect to each M+C plan that it offers. These requirements generally are the same for each type of M+C plan—including M+C non-network MSA plans and M+C PFFS plans.

The grievance, organization determination, and appeal requirements for M+C organizations that are set forth in this interim final rule are largely based on the existing rules for managed care organizations under part 417, Subpart Q, Beneficiary Appeals. This is in accord with section 1856(b)(2), which directs that the M+C standards be based on the analogous standards established under section 1876, as long as they are consistent with the requirements in part C. Moreover, we note that to some extent the statutory requirements themselves reflect policies contained in the existing part 417 requirements. For example, the requirements under section 1852(g)(3) concerning expedited organization determinations and reconsiderations essentially incorporate the expedited review procedures that were issued in HCFA's April 30, 1997 final rule with comment (62 FR 23368). (That final rule established expedited review processes for organization and reconsidered determinations, and clarified that the definition of an organization determination includes discontinuations of service.)

Thus, the significant differences between the grievance and appeal requirements that apply under the M+C program and the existing requirements in subpart Q of part 417 are: (1) changes that are explicitly mandated under the statute, such as the requirement under section 1852(g)(4) that HCFA contract with an independent outside entity to review coverage denials; and (2) changes that implement statutory intent, such as the reduced timeframe for reconsiderations, which is consistent with both the discretion provided under section 1852(g)(2)(A) and Congress' expectations as stated in the BBA conference report. (As discussed below, the conference report states that the Conferees ''* * * assume that the Secretary will address the issue of [reconsideration] timeframes in the Part C regulations'' and intend that the Secretary adopt timeframes that are shorter than those in existing regulations. See H.R. Rep. No. 105–217, pg. 605 (1997).) The only other substantive changes contained in these requirements are the incorporation into the regulations of several limited policy clarifications that have been issued by HCFA as implementing instructions pursuant to our April 30, 1997 final rule. These changes are discussed in detail below.

In addition to these limited substantive changes, we have also taken the opportunity to make numerous editorial and organizational changes in adopting the part 417 regulation language on beneficiary appeals for

purposes of the M+C program. For example, we have added material that summarizes the rights of M+C enrollees, and we have established distinct sections that clearly explain the timeframe and notice requirements for standard and expedited organization determinations. These types of changes do not affect the rights of beneficiaries or the responsibilities of M+C organizations with regard to grievances, organization determinations, and appeals, but we believe they can help to ensure that these rights and responsibilities are more clearly understood within the managed care community.

2. General Provisions (§§ 422.560–522.562)

Subpart M begins with an introductory section (§ 422.560) that simply sets out the statutory basis and scope for the requirements that follow. Although this material is generally shorter and more concise than the similar provisions of subpart Q in part 417, we are now specifying under § 422.560(b) that the rules concerning notice of noncoverage on inpatient hospital care and immediate peer review organization (PRO) review procedures for noncoverage determinations fall within the scope of the M+C subpart M requirements.

Section 422.561 then sets forth several definitions for terms used in the subpart. Note that some definitions previously located in subpart Q of part 417 (such as ''ALJ'') have now been included in § 400.200, rather than in part 422, since they constitute definitions that apply for all Medicare and Medicaid purposes. Terms included here that are not defined in existing part 417 include ''appeal,'' ''authorized representative,'' ''enrollee,'' ''grievance,'' and ''physician.'' For the most part, these definitions are self-explanatory; they do not impose any new requirements on M+C organizations. For example, we clarify that an ''authorized representative'' is an individual authorized by an enrollee to act on his or her behalf in obtaining an organization determination, or in dealing with any levels of the appeal process, subject to the Social Security regulations in 20 CFR part 404, subpart R. We also specify that, for purposes of subpart M, the term ''enrollee'' includes an enrollee's authorized representative. Together, these definitions should clarify that the rights of enrollees with respect to grievance and appeal procedures can consistently be exercised for them by their authorized representatives, except where specifically proscribed in the regulations. We also establish that ''physician'' is defined according to section 1861(r), which is the standard definition for both original Medicare and the M+C program.

Section 422.562, General Provisions, provides an overview of the rights and responsibilities of M+C organizations and M+C enrollees with respect to grievances, organization determinations, and appeals. The responsibilities of M+C organizations, under § 422.562(a), essentially parallel those in existing § 417.604(a). We have added a provision stating that if an M+C organization delegates any of its responsibilities under subpart M to another entity or individual through which the organization provides health care services, the M+C organization is ultimately responsible for ensuring that the applicable grievance and appeal requirements are still met. This concept is explicitly stated in section 1852(f) concerning grievance procedures, and we believe it is equally germane for purposes of organization determinations and appeals. An M+C organization's responsibility for functions that it delegates is also established under the contract requirements set forth in § 422.502(i). (Although we do not encourage M+C organizations to delegate their grievance, organization determination or appeal responsibilities, we recognize that particularly for an M+C non-network MSA plan or an M+C PFFS plan, an organization offering such a plan may choose to delegate some of these responsibilities to local entities that can meet the applicable subpart M requirements.)

Section 422.562(b) explains the basic rights of M+C enrollees under subpart M and provides regulatory references to the sections that fully explain the relevant rights. This section does not establish any rights beyond those now available under the part 417 rules, but consolidates general information about enrollees' rights into a central location in the regulations.

Like the part 417 regulations, the general provisions section concludes with brief sections addressing the applicability of requirements in subpart M and the applicability of other regulations under title II of the Act.

3. Grievance Procedures (§ 422.564)

As noted above, section 1852(f) requires that each M+C organization provide ''meaningful procedures for hearing and resolving grievances.'' There is no explicit indication in the statute of what constitutes a grievance; however, given the provision in section 1856(b)(2) for basing Part C standards on standards under section 1876, we have retained the meaning of grievance used in part 417. We have defined this term in § 422.561 as any complaint or dispute other than one that involves an ''organization determination'' (as described under § 422.566(b)).

An enrollee might file a grievance if, for example, the enrollee received a service but believed that the demeanor of the person providing the service was insulting or otherwise inappropriate. Also, as specified under §§ 422.570(d)(2)(ii) and 422.584(d)(2)(ii), grievance procedures would apply when an enrollee disagrees with an M+C organization's decision not to comply with an enrollee's request to expedite an organization determination or a reconsideration. Under § 422.564(a), we are requiring that an M+C organization must resolve grievances in a timely manner and that procedures for doing so must comply with any guidelines established by HCFA. This guidance would include forthcoming instructions, rulemaking, and requirements built into HCFA's Quality Improvement System for Managed Care (QISMC). (See section II.D of this preamble for more information about QISMC.) Section 422.564(b) then clarifies that grievance procedures are separate and distinct from appeal procedures, which address organization determinations. We also clarify under § 422.564(c) that the PRO complaint process under section 1154(a)(14) addresses quality issues, but is separate and distinct from the M+C organization's grievance procedures.

Although we have not in the past outlined detailed requirements for a plan's grievance procedures, we considered doing so in this interim final rule as a means of implementing the requirement under section 1852(f) for meaningful grievance procedures. Accordingly, we consulted with the managed care industry as well as beneficiary advocacy groups, reviewed comments we received from the public, and looked to recent standards in this area, such as those developed by the National Association of Insurance Commissioners (NAIC). (NAIC has developed and adopted a Model Grievance Act setting forth standards for grievance procedures that include timeframes for the resolution of quality-related issues.) We also recognize that section 1852(c)(2)(C) requires organizations to provide data on the number of grievances and their disposition in the aggregate upon an enrollee's request, and we believe timely processing of grievances is necessary to assist in consistent data reporting. Thus, we considered requiring certain timeframes for

addressing grievances and contemplated further clarification of the definition of a grievance.

However, due to limited time for rulemaking, input we received from the public opposing mandated grievance procedures, and our understanding that extensive research is underway concerning State grievance requirements (the results of which should be available in the very near future), we have decided not to prescribe specific timeframes for grievances in this rule and instead to consider doing so through proposed rulemaking. We plan to address such issues through a future proposed rule. At this time, we welcome comments on the necessary elements of a meaningful grievance procedure, including recommended timeframes, the types of issues that should be considered grievances, an expedited grievance process, independent review of grievances, reconsideration of grievances, and the type of notification enrollees should receive concerning the outcome of their grievance.

4. Organization Determinations (§§ 422.566 Through 422.576)

Section 1852(g) requires an M+C organization to establish procedures for hearing and resolving disputes between the organization and its Medicare enrollees concerning organization determinations. These rights are similar to those available to beneficiaries under original Medicare, except that under the M+C program the initial level of review is typically conducted by the organization itself rather than by a PRO, intermediary, or carrier.

(For the convenience of the reader, we are presenting below a chart offering a sequential overview of the available procedures and related timeframes associated with service-related organization determinations and appeals. This chart is for illustrative purposes only, and certain details (such as when extensions are permissible and timeframes for requests for payment) have been omitted for ease of presentation. For a full description of the applicable requirements, please consult the preamble material that follows and the regulations set forth in subpart M of part 422. Although the chart reflects the maximum allowable timeframes available to an M+C organization under the M+C regulations (for service requests), we emphasize that the primary applicable requirement, as discussed in detail below, is that an M+C organization make a determination as expeditiously as the enrollee's health condition requires. In addition, note that maximum timeframes for an M+C organization to make a payment-related determination are somewhat longer than for service-related determinations, as is also discussed below.)

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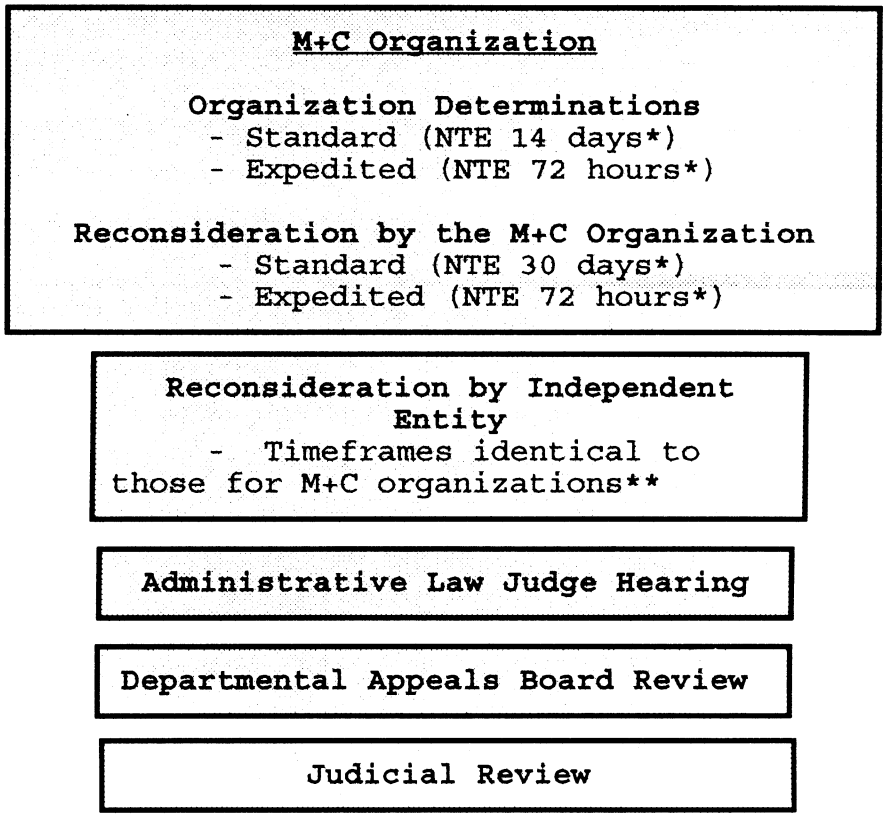
M+C ORGANIZATION DETERMINATION AND APPEAL PROCESS FOR SERVICE-RELATED REQUESTS



* For all service-related requests, an M+C organization must render determinations "as expeditiously as the enrollee's health condition requires," but not to exceed (NTE) the timeframes noted above.

** As discussed below, the timeframe requirements for standard and expedited reconsiderations by the independent entity will be established through contract.

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In accordance with section 1852(g)(1), § 422.566 begins by specifying that an M+C organization must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive and the amount, if any, that an enrollee must pay for a health service. We note that under section 1852(g)(1), the issues that must be addressed through an organization determination include an enrollee's entitlement to ''receive a health service *under this section*.'' (Emphasis added.) Section 1852(a) describes basic benefits that M+C organizations must offer, as well as supplemental benefits that organizations may offer. Supplemental benefits may either be provided to all enrollees on a mandatory basis (with the Secretary's approval) or provided at the enrollee's option. In both cases, the enrollee pays for supplemental benefits. Disputes involving supplemental benefits that are mandatory for all enrollees in a plan will be organization determinations and subject to the appeal process, as similar benefits were under part 417. We believe, however, that optional supplemental benefits should also be included in the meaning of ''health services under [section 1852]'' and disputes involving these types of benefits should be the subject of organization determinations and the appeal process. This policy, which is incorporated into § 422.566(a), represents a departure from existing part 417 requirements, where disputes concerning optional supplemental benefits are not the subject of organization determinations and must be resolved only through grievance procedures. Section 422.566(b) then lists actions that are organization determinations, consistent with existing § 417.606(a) (except for new language to reflect the inclusion of optional supplemental benefits and the explicit mention of payment for post-stabilization care, along with payment for emergency or urgently needed services, which appear already in § 422.606(a)).

Section 422.568 includes the standard timeframe and notice requirements for organization determinations. Note that this section, in conjunction with §§ 422.570 and 422.572, reflect a major reorganization of the requirements in existing §§ 417.608 and 417.609. This reorganization was necessary both to help clarify the different timeframe and notice requirements that apply for expedited determinations as well as to facilitate the addition of several new BBA requirements (which are discussed below).

The primary substantive change in § 422.568 is the requirement under § 422.568(a) that an M+C organization must make a determination with respect to an enrollee's request for service as expeditiously as the enrollee's health status requires, and in no case later than 14 calendar days after the organization receives the request. As discussed in detail below in section II.M.6 of this preamble, this new requirement emphasizes making determinations consistent with an enrollee's health needs, while also providing for a reduction in the maximum time allowed to make a determination from 60 days, as reflected in § 417.608(a), to 14 days. In conjunction with the reduced timeframe for making an organization determination, we are also providing that the M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence from noncontract providers may change an M+C organization's decision to deny). The M+C organization must include written justification for the extension in the case file. The length of the extension period is consistent with the extensions currently allowed under part 417 for expedited organization determinations.

We note that the maximum timeframes for both organization determinations and for reconsiderations are now reckoned in ''calendar days,'' as opposed to ''working days,'' in order to be unambiguous and consistent with the statute. In addition, under § 422.568(b), we have specified that timeframes for requests for organization determinations on payment issues are identical to the ''prompt payment'' requirements set forth under § 422.520. Thus, for issues relating to payment, the requirements are as follows: (1) For ''clean claims,'' an M+C organization must make a determination regarding the claim within HCFA's current ''clean claim'' rules, that is, 95 percent of clean claims must be paid within 30 calendar days after receipt of the request for payment. (As defined in § 422.500, ''clean claims'' are claims that have no defect, impropriety, lack of any required substantiating documentation, or particular circumstances requiring special treatment that prevents timely payment.) (2) For all other claims, an M+C organization must make a determination regarding the claim within 60 calendar days after receipt of the request for payment.

Consistent with section 1852(g)(1)(B), § 422.568(c) and (d) require that an M+C organization issue written notification for all denials, including the specific reasons for the denial in understandable language, information regarding the enrollee's right to either an expedited or standard reconsideration, and a description of both the expedited and standard review processes, as well as the rest of the appeal process.

Sections 422.570 and 422.572 set forth the requirements for M+C organizations with respect to expedited determinations. Section 1852(g)(3)(A) specifically allows either an enrollee or a physician to request an expedited organization determination or reconsideration, regardless of whether the physician is affiliated with the M+C organization. We have reflected this provision in §§ 422.570(a) (for expedited organization determinations) and 422.584(a) (for expedited reconsiderations). We have also addressed the issue of the circumstances under which a physician can request expedited review for an enrollee. HCFA currently allows any physician to request an expedited organization determination without being appointed as an enrollee's authorized representative. In contrast, HCFA requires that a physician be an enrollee's authorized representative in order for the physician to request an expedited reconsideration on the enrollee's behalf. We have made this distinction because, in the context of an organization determination, we regard the physician as a provider who is requesting a service for his or her patient. In the context of a reconsideration, on the other hand, we believe the physician is serving as the enrollee's representative in the first level of the appeal process.

We have decided to continue this current policy, and have reflected in § 422.570(a) that any physician can request an expedited organization determination, while § 422.584(a) provides that a physician who requests an expedited reconsideration must be acting on behalf of the enrollee as an authorized representative. We would also like to make it clear that, in any case in which a physician is only supporting an enrollee's request for expedited review, the physician does not need to be the enrollee's authorized representative.

As mentioned above, the requirements for expedited organization determinations and the like requirements for expedited reconsiderations were the subject of HCFA's April 30, 1997 final rule. Section 1852(g)(3) is modeled to a large extent on our existing requirements. For example, section 1852(g)(3)(B)(ii)

explicitly states that an M+C organization must expedite its determination (or its reconsideration of a determination) if a physician has requested the expedited review and has indicated, either orally or in writing, that the application of a standard timeframe for a determination (or reconsideration) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. This new statutory provision reflects the current provisions in part 417. Sections 417.609(c)(4) and 417.617(c)(4) require that an HMO or CMP grant a physician's request for expedited review; however, they do not require that the physician make any statements about the enrollee's health, as the physician must under section 1852(g)(3)(B)(ii). In effect, the statute now requires that an M+C organization must expedite a determination at the physician's request, that is, providing that the physician's request indicates the possibility of serious jeopardy to the enrollee.

Section 422.570(b)(2) specifies that a physician may provide written or oral support for a request for expedition, and under § 422.570(c)(2)(ii), we clarify that when requests for expedited organization determinations are made or supported by a physician, the M+C organization must grant the request if the physician indicates that the enrollee's health could be jeopardized. In any case in which a physician has not initiated the request, but supports it, we regard the physician as having joined in the request and, in effect, as being a co-requestor. (We note that in a case when an enrollee submitted a request for an expedited organization determination but did not know that physician support could automatically expedite a determination, an enrollee or a physician may submit a subsequent request, including the physician's statement of support, for an expedited organization or reconsidered determination.)

These sections also incorporate several details necessary to clarify current policy, such as the provision in § 422.568(d)(1) that an M+C organization automatically transfer a denied request for an expedited organization determination to the standard 14-day timeframe described in § 422.568(a), and the requirement under § 422.570(d)(2)(ii) that an M+C organization inform the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision not to expedite. We also require under § 422.570(c)(1) that an organization establish an efficient and convenient means for individuals to submit oral or written requests for expedited organization determinations and document any oral requests. Generally, in accordance with the provisions of § 422.570(b)(1), we would expect that such requests would be submitted directly to the M+C organization. However, because we recognize that some organizations may already have established or may wish to establish other convenient procedures for accepting oral and written requests for expedited review, we clarify under § 422.570(b)(1) that procedures may involve submitting a request to another entity responsible for making the determination, as ''directed by the M+C organization.''

Under section 1852(g)(3)(B)(iii), an M+C organization must notify the enrollee (and the physician involved, as appropriate) of an expedited determination. The requirement to notify the physician is similar to one in § 417.609(c)(3), which requires of an HMO or CMP ''notification of the enrollee, and the physician as appropriate.'' This requirement is set forth in § 422.572(a). Section 1852(g)(3)(B)(iii) also requires that the M+C organization notify the enrollee and physician of an expedited determination under time limits established by the Secretary, but not later than 72 hours after receiving the request (or receiving the information necessary to make the determination), or such longer period as the Secretary may permit in specified cases. Under this authority, we are able to retain in § 422.572(a) the existing 72-hour timeframe for expedited review that appears in § 417.609(c)(3). Also, we have exercised our discretion to allow in § 422.572(b) an M+C organization to extend the 72-hour deadline for expedited review by up to 14 calendar days if the enrollee requests the extension or if the organization finds that additional information is needed and the delay is in the interest of the enrollee.

Thus, the authority in section 1852(g)(3)(B) has allowed us to retain the recently promulgated regulations on expedited determinations with only a few clarifications and minor technical changes (for example, we have changed the 10 working day extension in § 417.609(c)(3) to 14 calendar days, to be consistent with how we are counting days under the other section 1852 provisions). We have added to the regulation an example of the type of reason for which an extension may be granted, and we have specified that an M+C organization must notify an enrollee of a determination as expeditiously as the enrollee's health care needs require but no later than upon expiration of the extension.

We have also added a provision in both §§ 422.570(f) and 422.584(f) to prohibit an M+C organization from taking or threatening to take any punitive action against a physician acting on behalf or in support of an enrollee in requesting an expedited organization determination or reconsideration. Since publication of our April 30, 1997 final rule, several national organizations (including the American Medical Association and the American Association of Retired Persons) have expressed strong support for a general prohibition that would prevent retaliation against physicians who act on behalf of or in support of enrollees to expedite reviews. Moreover, we believe that this prohibition complements the anti-gag rules incorporated into subpart E of this interim final rule.

Section 422.574 identifies the parties to an organization determination. The statute does not specify who can ask for an organization determination involving the rights of an M+C enrollee to certain health services. Section 1852(g) does specify that an M+C organization must reconsider a determination upon the request of the enrollee, and either the enrollee or a physician can request an expedited reconsideration. The enrollee specifically has the right to appeal a reconsidered determination under section 1852(g)(5), a provision that is almost identical to the appeal provision in section 1876(c)(5)(B) for HMO and CMP enrollees.

We are interpreting these provisions in the same manner as we interpreted them in part 417 to include not just the enrollee, but also to allow other parties to exercise those rights. Section 417.610 lists as parties to an organization determination not just the enrollee, but certain physicians and other providers who are assignees of the enrollee, legal representatives of a deceased enrollee's estate, and the broad category of any other entity determined to have an appealable interest in the proceeding. These parties can continue to have an interest in the proceedings throughout each level of an appeal. We have retained this provision in § 422.574, except that we have modified § 417.610(d) to include any *provider* or entity determined to have an appealable interest. We have also specifically excluded the M+C organization, since we believe that this entity constitutes the decision maker, and as such is not a party to an organization determination.

5. Reconsiderations by an M+C Organization (§§ 422.578 Through 422.590)

If a decision regarding a request for payment or service is unfavorable (in whole or in part) to the enrollee, the enrollee or any other party to an organization determination as listed in § 422.574 who is dissatisfied with the organization determination may request that the M+C organization reconsider the decision. Reconsiderations represent the first step in the appeal process. The reconsideration process encompasses both standard and expedited reconsiderations, as described under §§ 422.582 and 422.584. The timeframe and notice requirements for reconsiderations are set forth under § 422.590.

One important distinction between organization determinations and reconsiderations is that an M+C organization issues a reconsidered determination only if the reconsideration is entirely favorable to the enrollee. As discussed in detail below, § 422.590(a)(1) now requires that with respect to standard reconsiderations concerning requests for service, an M+C organization must issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 30 calendar days after it receives the request for reconsideration. (As with organization determinations, we are also providing under § 422.590(a) that the M+C organization may extend the timeframe by up to 14 calendar days if the enrollee requests the extension or if the organization justifies a need for additional information and how the delay is in the interest of the enrollee.) Under § 422.590(b)(1), for standard reconsiderations involving requests for payment, the M+C organization must issue any fully favorable determination no later than 60 calendar days from the date it receives the request for the reconsideration. In the case of expedited reconsiderations (which involve only requests for services), § 422.590(d)(1) requires that an M+C organization issue any determination that is entirely favorable to the enrollee as expeditiously as the enrollee's health condition requires but no later than 72 hours after it receives the request for expedited reconsideration, again with the possibility of a 14-day extension as described in § 422.590(d)(2). If, however, the M+C organization's reconsideration results in an affirmation, in whole or in part, of its original adverse organization determination, this decision is automatically subject to further review by an independent entity contracted by HCFA. (Again, the timeframe within which an M+C organization must reconsider a standard or expedited case has been tied to the enrollee's health needs for service requests, subject to either a 30-day or 72-hour maximum (with a possible 14-day extension), while the timeframe remains at 60 days for reconsideration requests involving payment.)

Section 1852(g)(4) of the Act requires HCFA to contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm, in whole or in part, an M+C organization's denial of coverage. Thus, unless an organization completely reverses its coverage denial, the M+C organization must prepare a written explanation and refer the case to the independent review entity for a new and impartial determination concerning the payment or service at issue. This requirement is consistent with existing policy. Under § 417.620, an HMO or CMP that recommends partial or complete affirmation of its adverse determination must prepare a written explanation and send the entire case to HCFA, so that HCFA can make the reconsidered determination. We have in the past contracted with an independent outside entity, the Center for Health Dispute Resolution (CHDR), to perform this function.

For standard requests for services, § 422.590(a)(2) requires that the M+C organization send the case to the independent review entity as expeditiously as the enrollee's health requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or the date of an expiration of an extension). For standard requests for payment, § 422.590(b)(2) allows the M+C organization 60 calendar days from the date it receives the request to send the case to the independent review entity. In instances involving expedited requests for reconsideration, § 422.590(d)(5) requires that the M+C organization forward its decision to the independent entity as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation of the adverse organization determination.

Section 1852(g)(2)(B) requires that any reconsideration that relates to a determination to deny coverage based on a lack of medical necessity must be made only by ''a physician with appropriate expertise in the field of medicine which necessitates treatment.'' We have interpreted this requirement in § 422.590(g)(2) to refer to a physician with an expertise in the field of medicine that is appropriate for the services at issue. The statute also requires that the physician be one other than the physician involved in the initial determination. We believe this requirement is implicit in the provision in § 422.590(g)(1) that the reconsideration be conducted by a person not involved in making the organization determination.

For the most part, the procedures outlined above are consistent with the existing part 417 requirements and are carried over into subpart M of part 422—all significant discretionary changes (such as the timeframe reductions) as well as statutory requirements (such as required physician review of certain coverage denials) are discussed in this preamble. We also are implementing several changes in the reconsideration requirements that are analogous to those described for organization determinations, such as the requirement under § 422.584(d)(1) that an M+C organization automatically transfer a denied request for an expedited reconsideration to the standard 30-day timeframe described in § 422.590(a). In addition, § 422.590(e) requires that if an M+C organization refers a case to the independent entity, it must concurrently notify the enrollee of that action.

6. Reduction of Timeframes for Standard Organization Determinations and Reconsidered Determinations

As noted above, section 1852(g)(1)(A) requires that M+C organizations make organization determinations ''on a timely basis.'' For standard (non-expedited) reconsiderations, section 1852(g)(2)(A) specifies that a decision must be made no later than 60 days after the enrollee's request, but the Act provides the Secretary with discretion to reduce the timeframe. Again, the BBA conference report (H.R. Rep. No. 105–217, at pg. 605 (1997)) indicates Congress' understanding that HCFA was developing proposed regulations that would reduce existing timeframes and that these efforts could instead be incorporated into the regulations implementing the M+C program. Consequently, we have decided to exercise such discretion and to reduce the timeframes within which M+C organizations must render both standard organization and reconsidered determinations involving requests for service.

In researching this issue, we found widespread support for reducing timeframes for standard determinations in both medical journals and reports

from other independent entities. For example, the Physician Payment Review Commission's (PPRC) 1996 Annual Report to Congress listed ''the timeliness of the process, especially for pre-service denials'' as one of the areas requiring improvement in the current appeal process. PPRC reported that ''[c]onsiderable delays are built into the [appeal] process.'' Likewise, the Medicare Rights Center (MRC) recently recommended that HCFA require health plans to make non-expedited organization determinations within 10 days of receiving the request. The MRC also recommended that HCFA require health plans to make non-expedited reconsiderations within 20 days.

The 60-day timeframes in part 417 for organization and reconsidered determinations were based on the original fee-for-service Medicare appeal process. However, this process is mostly retrospective. In coordinated care plans, preservice requests for organization determinations exceed the number of retrospective requests. Reduced timeframes often are of critical importance—particularly when an individual is awaiting prior authorization for a service. Therefore, we believe there is a compelling need to reduce the current timeframe of 60 days for determinations regarding the provision of services in M+C organizations.

Options Considered

In developing this rule, we consulted with beneficiary advocacy groups and the managed care industry concerning several policy options, and reviewed comments received from the public. The groups agreed that the current 60-day timeframe to issue organization and reconsidered determinations was too long. A representative of HCFA's independent contractor, the Center for Health Dispute Resolution (CHDR), also agreed that 60 days was too long for processing determinations.

Beneficiary advocacy groups indicated that the timeframe for rendering standard service-related organization determinations and reconsiderations should be no more than a total of 20–30 days. Advocates reported (and our research supports) that many States require determinations within 30 days. Additionally, beneficiary advocates indicated strong support for the judgment of the United States District Court for the District of Arizona in *Grijalva, et al.* v. *Shalala* (Civ. 93–711, 1997). That case involved the appeal rights of Medicare beneficiaries who were members of HMOs and had their requests for services denied. The court's judgement in *Grijalva* prescribes various procedures to be used for beneficiary appeals in Medicare managed care programs, including the requirement that the HMO make a decision within 5 days, with an opportunity for a 60-day extension if there are exceptional circumstances.

Representatives of the managed care industry recommended that we adopt the National Committee for Quality Assurance's (NCQA) standard of 10 working days (or 14 calendar days) for organization determinations—with an opportunity for an extension. It was also noted that decisions on reconsiderations often take more time than organization determinations. The industry representatives agreed that, in many cases, plans process reconsiderations in less than 30 days, but that often times, additional time is needed to gather information (e.g., medical records). The industry representatives noted that in some instances, allowing extra time to collect information is advantageous to the beneficiary.

Based on all of this information, we are implementing revised requirements from those in part 417 for an M+C organization when it issues standard organization determinations or reconsiderations. These revised requirements include a reduction in the maximum timeframes from 60 days to 14 days for standard organization determinations involving requests for service, and from 60 days to 30 days for standard reconsiderations involving requests for service. (In both cases, 14-day extensions would be permissible under certain circumstances, as discussed above.) More important, §§ 422.568 and 422.590 establish for the first time the requirement that M+C organizations make both their organization and reconsidered determinations as expeditiously as the enrollee's health condition requires. We believe that this emphasis on the health needs of the individual enrollee is consistent with the statutory requirement that determinations be made on a timely basis. Thus, the fact that an organization makes a determination on a service-related issue within 14 days does not necessarily constitute compliance with the regulations if there is evidence that an earlier determination was necessary to prevent harm to the enrollee's health.

7. Reconsiderations by an Independent Entity (§§ 422.592 and 422.594)

Section 1852(g)(4) requires the Secretary to contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part. HCFA has held such a contract for services from an independent review entity for 9 years. Section 422.592 reiterates the statutory requirement. It also articulates the principle that the independent entity must conduct reviews as expeditiously as the enrollee's health requires, but not to exceed the deadlines specified in its contract with HCFA.

For standard reconsiderations, the contractor historically has been able to process most cases within 30 days. We will require the contractor to meet the standard articulated for M+C organizations at section 422.590; that is, subject to considerations of medical exigency, the contractor must process standard reconsiderations within 30 days, with the possibility of an extension. As part of our new requirement to collect and report information regarding beneficiary appeals, we will monitor all exceptions to deadlines and reasons for delay. In cases in which the delay is due to the failure of the M+C organization to supply the contractor with requested information in a timely manner, we will generally instruct the contractor to find in the beneficiary's favor on any issue that it cannot decide without the information in question. (When an M+C organization has conducted a reconsideration, it presumably will have already collected all the relevant documents and other information needed to make the decision. However, our experience demonstrates that the independent reviewer must sometimes request additional material in order to have a complete record of the dispute.)

For expedited cases, we will require the contractor to make a decision as quickly as the enrollee's condition requires, or within 72 hours (with the possibility of an extension under certain circumstances), in accordance with the expedited reconsideration requirements for M+C organizations under § 422.590(d). As with standard reconsiderations, we will monitor cases that exceed this deadline along with the reasons for the delay. If any delay is due to the failure of the M+C organization to supply the contractor with requested information in a timely manner, we will generally instruct the contractor to find in the beneficiary's favor on any issue that it cannot decide without the information in question.

In order to provide more guidance to both our contractor and the M+C organizations with which we will contract, we will work with them and other interested parties to develop common guidelines for identifying those cases that require immediate attention due to the enrollee's health condition.

These guidelines will build upon, but not be limited to, the criteria that M+C organizations must use to evaluate whether a case should be expedited, currently contained in § 422.570(c)(2). We will issue this information as part of forthcoming manual instructions.

8. Administrative Law Judge (ALJ) Hearings, Departmental Appeals Board (DAB) Hearings, and Judicial Review (§§ 422.600 Through 422.612)

If the independent reviewer's reconsidered determination is not fully favorable to the enrollee, any of the parties listed in § 422.574 has a right to request a hearing before an ALJ of the Social Security Administration if the amount remaining in controversy is $100 or more. (Note that the M+C organization does not have a right to request a hearing before the ALJ.) If the ALJ hearing does not result in a fully favorable determination, any party (including the M+C organization) may request that the Appeals Council of the DAB review the ALJ decision. Following the administrative review process, any party (including the M+C organization) is entitled to judicial review of the final determination if the amount remaining in controversy is $1,000 or more. In establishing the requirements for M+C organizations, we have clarified and adopted the existing requirements in part 417, with one exception. That is, consistent with section 1852(g)(5), we require under § 422.612(a) that a party who wishes to request judicial review of an ALJ's decision must notify the other parties involved.

9. Effectuation of a Reconsidered Determination or Decision (§ 422.618)

Based on public reaction to our April 30, 1997 final rule, we believe there may be a need for explicit regulatory requirements concerning an M+C organization's effectuation of (that is, an organization's compliance with) an appeal determination or decision. Therefore, we are including at § 422.618 (and referencing at § 422.590(a)(1) and (b)(1)) several requirements that constitute a restatement of HCFA's longstanding policy in this regard (with a corresponding timeframe reduction from 60 to 30 days in the case of service-related reconsiderations). (See sections 2405.4 and 2405.5 of the HMO/CMP Manual Transmittal 6, issued in March, 1991.) Specifically, § 422.618(a)(1) requires that if, on reconsideration of a request for service, an M+C organization reverses its adverse organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health requires, but no later than 30 calendar days after the date the M+C organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(a)(1)). For reconsideration of requests for payment, § 422.618(a)(2) requires that if an M+C organization reverses its adverse organization determination, the organization must pay for the service no later than 60 calendar days after the date the M+C organization receives the request for reconsideration. Similarly, under § 422.618(b), if an M+C organization's adverse organization determination is reversed in whole or in part by the independent entity's reconsideration or at a higher level of appeal, the M+C organization must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date the M+C organization receives notice reversing its organization determination. The M+C organization must also inform the independent, outside entity that it has effectuated the decision.

10. Noncoverage of Inpatient Hospital Care—Notice and PRO Review (§§ 422.620 and 422.622)

Under § 422.620, we are largely incorporating the existing requirements under § 417.440(f) concerning notice of noncoverage of inpatient hospital care. Section 417.440(f) requires that if an enrollee in an HMO or CMP is a hospital inpatient, the enrollee remains entitled to inpatient care until he or she receives notice that the care is no longer covered. We have revised this provision, however, to make it clear that inpatient services only continue to be covered until there is a notice of noncoverage in situations in which the hospital admission was authorized in the first instance by the M+C organization or in which the admission constituted emergency or urgently needed care, as described in §§ 422.2 and 422.112(b). This clarification is warranted in light of the fact that an M+C organization offering an M+C non-network MSA or private fee-for-service plan has the right to deny coverage retroactively for a hospital stay involving nonemergency or nonurgently needed care on the grounds that it was not medically necessary. Also, this would make it clear that an M+C organization does not have to make payment under an MSA plan if the deductible has not been satisfied.

Section 422.622 explains our requirements with respect to an enrollee's right to PRO review of a determination by an M+C organization or a hospital that inpatient care is no longer necessary.

Under existing § 417.605, Medicare managed care enrollees have two protections available to them when they believe they are being discharged prematurely from a hospital—immediate PRO Review or an HMO or CMP's internal expedited appeal process. Under § 417.604(b), enrollees may elect one appeal right or the other; exercising one right eliminates the right to the other.

We believe that the PRO review process offers significant advantages to enrollees, most significantly the protection from financial liability for a continued hospital stay until noon of the calendar day following the day the PRO notifies the enrollee of its review determination. Additionally, PROs generally communicate directly with the Medicare enrollee (or authorized representative) during the review, conduct their reviews of an alleged premature discharge within 3 days, and use nurses and physicians to conduct the reviews. In contrast, enrollees who file for an expedited review with the managed care organization are not protected from financial liability during an appeal. The HMO or CMP has 72 hours to conduct the review. If the organization is unable to issue a fully favorable decision to the enrollee, the case file will be forwarded to the independent contractor.

In developing the M+C requirements with respect to this issue, we considered whether the regulations should require enrollees of M+C organizations to exercise their right to immediate PRO review. We consulted with representatives of both the managed care industry and beneficiary advocates. The groups with which we consulted indicated that the immediate PRO review process appears to be a better option for the enrollee. As noted previously, PRO review provides financial protection, direct communication between the PRO and the enrollee, and a decision that is generally rendered more quickly than a managed care plan's determination. However, we were not certain whether we should limit beneficiaries to one option. Particularly in the event that an enrollee misses the deadline for filing with the PRO, we believe that the enrollee should retain the option of filing an expedited appeal with the M+C organization.

Based on this review, we have concluded that the appropriate course is to draft the M+C requirements so as to make it clear that it is in the best interest of an M+C enrollee to request PRO review if the individual believes that he

or she is being discharged from a hospital prematurely. Thus, § 422.622(a)(1) specifies that: ''An enrollee who wishes to appeal a determination by an M+C organization or hospital that inpatient care is no longer necessary must request immediate PRO review. * * * An enrollee who requests immediate PRO review may remain in the hospital without further financial liability [subject to the provisions of § 422.622(c)]'' (until PRO review is completed). Section 422.622(a)(2) then provides that an enrollee who fails to make a timely request for PRO review still has the option of requesting an expedited reconsideration from the M+C organization, although the financial liability protections associated with the PRO review process do not apply. We believe that this regulatory construction makes it clear that enrollees are expected, for their own benefit, to avail themselves of the PRO review process, but does not eliminate the fall-back option of the M+C organization's expedited review process for those enrollees who fail to request PRO review on a timely basis.

We have made further revisions to the language in § 417.605 to adapt this provision to the new M+C MSA and private fee-for-service plan options. As discussed above in connection with the notice of non-coverage requirement in § 422.620, under these plan options, an M+C organization may not be aware that an enrollee has been hospitalized, and has the right to deny coverage of such a hospitalization on the grounds that the stay was not medically necessary. Also, in the case of an enrollee in an M+C MSA plan, the individual may not have reached the deductible under the plan, and therefore payment for medically necessary hospital services shall be applied to the deductible. We thus have made it clear in § 422.622(c)(1) that if an M+C organization did not authorize coverage of a hospital admission, and notifies the enrollee that a continued stay is not covered, the organization is not required to pay for services while the enrollee pursues an appeal with a PRO (that is, unless and until it is determined on appeal that the hospital stay should have been covered under the M+C plan). We have qualified this statement to provide that the M+C organization is obligated to pay for continued services if the enrollee was hospitalized in order to receive emergency services or urgently needed care as described in §§ 422.2 and 422.112(b), since these services do not require prior authorization.

In cases in which the *hospital* makes a determination that hospital services are no longer needed, section 1154(e)(4)(B) of the Act expressly precludes the hospital from charging a Medicare beneficiary for services during the period that a PRO is reviewing an appeal under section 1154(e). We have reflected this statutory provision in § 422.622(c)(2).

11. Conclusion

In developing the organization determination, appeal and grievance requirements for M+C organizations, we have undertaken a broad review of the existing Medicare managed care requirements. We have consulted with representatives of beneficiary advocacy groups and the managed care industry concerning several policy options. We believe that we have included in this interim final rule those improvements that were practical within the short timeframe allotted for rulemaking. In addition to the changes made in this rule, we intend to publish a notice of proposed rulemaking in the near future to implement a variety of other improvements in the M+C dispute resolution process.

Therefore, we welcome comments, concerns, and ideas on all issues discussed in this interim final rule, as well as on the overall organizational changes incorporated into these regulations. In particular, as noted above, we would appreciate comments on whether HCFA should specify requirements (such as timeframes) for meaningful grievance procedures. We also are seeking additional comments on establishing effective and efficient parameters as to when a reduction in services (for example, a reduction in prescription dosage, skilled nursing facility coverage, home health care or outpatient visits) constitutes a denial that gives rise to an obligation to provide written notice. Comments are also welcome on whether notification requirements should apply in all instances of service discontinuations, as opposed to only when an enrollee indicates that he or she disagrees with such a discontinuation, as provided under § 422.566(b)(4). Finally, we would appreciate input on categories of meaningful data elements for reporting plan-level grievances and appeals. We believe such comments can assist with our data collection and reporting efforts (as required by the BBA) and in promoting consistency at the plan level in data collection and reporting. We welcome all suggestions for other improvements to the M+C grievance, organization determination and appeal processes.

N. Medicare Contract Appeals

Subpart N of this interim final rule sets forth procedures for making and reviewing the following contract determinations: (1) A determination that an entity is not qualified to enter into a contract with HCFA under Part C of title XVIII of the Act; (2) a determination to terminate a contract with an M+C organization; and (3) a determination not to authorize a renewal of a contract with an M+C organization. Pursuant to at section 1856(b)(2), which provides for the adoption of standards under section 1876 to implement analagous provisions in the new Part C, the procedures set forth in subpart N of part 422 are for the most part modeled after the contract appeal procedures currently in place with regard to HMO and CMP contracts under section 1876, which are set forth at 42 CFR part 417 subpart R. We describe below the provisions of new subpart N of part 422 that are not identical to 42 CFR part 417.

Section 422.641 sets forth the contract determinations that are subject to the reconsideration and appeals procedures in subpart N.

Section 422.644(a) specifies that when HCFA makes a contract determination, it provides the M+C organizations written notice specifying reasons for the determination and M+C organization rights pursuant to a reconsideration.

Under, § 422.644(d) a HCFA notice that it has decided not to authorize an M+C organization contract renewal is sent to the M+C organization by May 1 of the current contract year. (Note that while this notice informs an M+C organizations of its right to appeal a decision not to authorize a renewal, a contract will not be renewed unless an affirmative notice *authorizing* renewal is sent by HCFA. *See* § 422.506(b)(2).) The May 1 deadline specified above should afford HCFA enough time to consider any M+C organization's request for reconsideration and still afford adequate time for HCFA to ensure the accuracy of its printed and electronic material utilized in the annual health fair.

If HCFA decides to terminate a contract under § 422.644(c) for reasons other than those specified at 422.510(a)(5) it must provide notice to the M+C organization by mail at least 90 days before the intended date of the termination. Consistent with section 1857(h)(2), which provides for immediate termination where there is an ''imminent and serious risk'' to enrollee health and pursuant to our rulemaking authority at section 1856(b)(1), in § 422.644(c) we also provide a separate notice timeframe for immediate terminations discussed in

§ 422.510(a)(5). See section K of this preamble. Pursuant to violations described in § 422.510(a)(5), HCFA will notify the M+C organization in writing that its contract has been terminated effective the date of the termination decision by HCFA. We believe that in instances where the life and physical well being of beneficiaries is in jeopardy, HCFA must have the ability to immediately sever its relationship with an M+C organization in order to protect beneficiaries and to safeguard taxpayer confidence in HCFA's administration of the Medicare program.

Section 422.646 states that initial contract determinations are final and binding unless the determination is reconsidered in a manner consistent with applicable requirements described in § 422.648. In § 422.650(b) we have shortened the deadline for filing a request for reconsideration to 15 days from the sixty days allowed for HMOs and CMPs under § 417.650(b), and have eliminated the provision made in § 417.650(c) for a deadline extension for good cause. We believe the time frames afforded under § 422.650 still provide M+C organizations sufficient time to prepare a request for reconsideration of the contract determination at issue, should the organization decide to do so.

As in the case of the deadline for requesting reconsideration, and based on our rulemaking authority at section 1856(b)(1), in § 422.662(b), we have shortened the 60 day time period for requesting a hearing under § 417.662(b) to 15 days. We also have again eliminated ''good cause'' extension authority that was found in § 417.662(c).

Like § 417.664(a), § 422.664(a) provides that the effective date of a determination to terminate a contract will be postponed until after a final decision is rendered on any M+C organization appeal. Section 422.664(b) also follows § 417.664(b) in providing that a request for a hearing will *not* postpone a decision not to authorize a contract renewal unless HCFA finds an extension of the contract past its expiration date consistent with the purposes of Part C. There are two significant differences between § 417.664 and § 422.664, however. First, as discussed below, § 417.664 provides that in the case of a termination only, the general rule is that the termination will be postponed until after an additional post-hearing decision level of review required under section 1857(h)(1)(B). Second, § 422.664(c) implements the ''imminent and serious risk to health'' exception in section 1857(h)(2), under which a termination can take effect immediately, and will not be postponed while an appeal is pursued. Specifically, when a contract termination decision is based upon § 422.510(a)(5), discussed in section K above, the termination is effective immediately. While the M+C organization still has the right to appeal the termination, this appeal will not prevent the termination from taking effect.

In § 422.670, pursuant to our rulemaking authority at section 1856(b)(1), we have added a requirement that the hearing officer establish a time and place for the hearing within 30 days of the date of their receipt of the request for a hearing. Again, this time constraint has been added because we believe it is necessary to impose time-weighted discipline on the reconsideration process that strengthens HCFA's enforcement capabilities while simultaneously enhancing beneficiary protections. Changing the time frame from the open-ended language provided under § 417.670 to the 30-day time frame provided at § 422.670 accomplishes these goals.

In § 422.692, we provide in the case of termination decisions only for an appeal from the hearing decision, as required under section 1857(h)(2) before a termination can take effect. We have provided for review of a hearing officer's decision by the Administrator, under similar procedures to those used for the Administrator's review of decisions of the Provider Reimbursement Review Board pursuant to § 405.1875.

O. Intermediate Sanctions

The M+C organization actions subject to intermediate sanctions and civil money penalties are substantially the same as those established at § 417.500 for section 1876 contracting plans. However, there are some exceptions. Since the 50/50 enrollment requirement has been dropped, so have the accompanying intermediate sanctions.

The BBA also contains additional sanction authority not found in § 417.500, which we are implementing in subpart O. First, the BBA retains and modifies new section 1876 intermediate sanction and civil money penalty authority originally enacted in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This authority has not been implemented in § 417.500. Under this new authority (in section 1876(i)(1) for HMOs and CMPs and in section 1857(g)(3) for the M+C program), intermediate sanctions and civil money penalties can be imposed on the same grounds upon which a contract could be terminated. *See* discussion of contract termination in sections K. and N. above. Under the section 1876 provision, the procedures now found in section 1857(h)(1), discussed in section N. above, applied to the new HIPAA sanction authority, and had to be followed before sanctions based upon this new HIPAA authority could be imposed. Under the BBA, however, sanctions based on the grounds for termination in section 1857(c)(2) can be imposed on the same terms as the sanctions in § 417.500. *See* section 1857(g)(3). As discussed above in section K., in § 422.510(a)(4) through (a)(11), we have identified specific M+C organization behaviors that we believe meet one of the broad grounds for termination in section 1857(c)(2). Under the authority in section 1857(g)(3) to impose sanctions where the grounds in section 1857(c)(2) exist, intermediate sanctions can be imposed for any of the violations identified in § 422.510(a), and we so provide in § 422.752(b).

Finally, private fee for service plans are subject to intermediate sanctions if they fail to enforce the balance billing limit that applies to charges to plan members by contracting providers. See discussion of these provisions in section IV. of this preamble.

The process for imposing all of the M+C intermediate sanctions will largely be the same as established under § 417.500. Under this process, when HCFA determines that a sanctionable violation has occurred, it notifies the M+C organization that enrollment and marketing must be suspended (or, alternatively, in the case of some violations, payment for new enrollees will be suspended) in 15 days, unless the organization provides evidence that HCFA's determination is incorrect. There is an exception to this 15 day delay in the effective date of the sanctions if HCFA determines that the M+C organization's conduct poses a serious threat to an enrollee's health and safety. *See* § 422.756(d)(2). In addition to or in place of these intermediate sanctions, civil money penalties may be imposed for the same underlying violations. For any of the violations that were previously set forth in § 417.500, and are now in § 422.752(a), the Office of Inspector General imposes civil money penalties in accordance with 42 CFR part 1003. In the case of the new HIPAA sanction authority discussed above, HCFA imposes civil money penalties, with the exception of a determination under § 422.510(a)(4), based upon fraudulent behavior by an M+C organization. In this latter case, OIG imposes civil money penalties.

P. Technical and Conforming Changes

This interim final rule makes a number of technical and conforming changes to part 422 subpart H (which was established by an interim final rule published on April 14, 1998 (63 FR 18124) and amended by an interim final rule published on May 7, 1998 (63 FR 25360) For example, we remove the definition of ''health care provider'' from subpart H. We do this because this rule establishes a definition of ''provider'' in subpart A of part 422 for purposes of the entire part that is exactly the same as the definition of ''health care provider'' appearing in subpart H. Further, as a conforming change, we then change ''health care provider'' wherever it appears in subpart H to ''provider.''

In addition to the additions and revisions to part 422 of our regulations discussed throughout this document, this interim final rule also makes a number of technical and conforming changes to the following parts of 42 CFR: 400, 410, 411, and 417. These changes, which are generally in the form of redesignations and nomenclature changes, are made in order to bring our regulations into conformity with the provisions of the section 4001 through 4006 of the BBA.

We have also made a conforming change to 42 CFR part 403 ''Special Programs and Projects,'' with regard to Medicare supplemental policies. As Medicare does not cover the total cost of providing medical care, approximately 75 percent of Medicare beneficiaries purchase or have available through their own, or a spouse's employment or former employment, some type of private supplemental health insurance coverage. This kind of insurance helps to pay for expenses, services, and supplies that Medicare either does not cover or does not pay in full such as coinsurance or deductible charges, prescription drugs, and some long term care services. This coverage is ordinarily referred to as Medicare supplemental (Medigap) insurance. The BBA, in section 4003, provides that an M+C plan is not considered a Medicare supplementary policy. Therefore, we are revising § 403.205 to specify that a Medicare supplemental policy does not include a M+C plan. We are aware of other provisions in that statute affecting the Medigap area, but those are included or will be covered under the National Association of Insurance Commissioners (NAIC) Model Standards in line with existing § 403.210. NAIC works with us to annually update the Model Standards with regard to changes to the Medicare supplemental insurance area.

Q. Transition Information for Current Medicare Program

Section 4002 of the BBA included a number of provisions that were effective upon enactment for eligible organizations with section 1876 contracts or section 1833 agreements or that would alter the requirements for those contractors that remained in force following the implementation of the M+C program. The provisions that were effective upon enactment were conveyed to current contractors through operational policy letters (OPLs) numbered 61, 63, and 65 and available to the public on HCFA's Internet homepage. Most of the provisions convey automatically with the publication of the Part C regulations, either contained in the newly-established part 422 or contained in conforming changes to part 417, while others simply created operational impacts during the transition year of 1998.

The BBA in section 4002(a) immediately changed the required enrollment composition of 50 percent Medicare and Medicaid, and 50 percent commercial under section 1876 to: (1) Consider only Medicare members for 50 percent of the enrollment, and (2) permit waiver of the requirement when it is ''in the public interest.'' All enrollment composition requirements for Medicare contractors are eliminated beginning with contract periods on or after January 1, 1999.

The BBA in section 4002(j) changed the definition of a health care prepayment plan (HCPP) to mean: (1) An organization that is Union or Employer sponsored; or (2) an organization that does not provide, or arrange for the provision of any inpatient hospital services. Current HCPPs must meet this definition on January 1, 1999 and new 1998 applicants must meet the definition as of the effective date of the HCPP agreement. Also, as of January 1, 1999, HCPPs are not required to meet Medigap requirements.

The BBA also affected section 1876 cost contracts. Upon enactment of the BBA (August 5, 1997), the Secretary may not enter into new section 1876 cost contracts, except for current HCPPs that converted to section 1876 cost contracts. Also, 1876 cost contracts may not be extended or renewed beyond December 31, 2002.

III. Medicare+Choice MSA Plans

A. Background

As noted above, among the type of M+C options available under section 1851(a)(2) of the Act is an M+C MSA plan, that is, a combination of a high deductible M+C insurance plan and a contribution to an M+C MSA. Section 1859(b)(3)(A) of the Act defines an MSA plan as an M+C plan that:

- Provides reimbursement for at least all Medicare-covered items and services (except hospice services) after an enrollee incurs countable expenses equal to the amount of the plan's annual deductible.
- Counts for purposes of the annual deductible at least all amounts that would have been payable under original Medicare if the individual receiving the services in question was a Medicare beneficiary not enrolled in an M+C plan, including amounts that would be paid by the beneficiary in the form of deductibles or coinsurance.
- After the annual deductible is reached, provides a level of reimbursement equal to at least the lesser of actual expenses or the amount that would have been paid under original Medicare if the individual receiving the services in question was a Medicare beneficiary not enrolled in an M+C plan, including amounts that would be paid by the beneficiary in the form of deductibles or coinsurance.

Eligible individuals may enroll in M+C MSA plans effective January 1, 1999. Section 1859(b)(3)(B) sets the maximum annual deductible under an M+C MSA plan for 1999 at $6,000, with changes for future years to be based on the national per capita M+C growth percentage established under section 1853(c)(6). (See section II.F of this preamble.) In this interim final rule, we are seeking comment regarding establishing, pursuant to our general authority under section 1856(b)(1), a minimum deductible under an M+C MSA plan. As discussed below, one possibility would be to establish a minimum deductible equal to the projected actuarial value of the average per capita copayment under original Medicare, rounded to the nearest $50.

Section 4006 of the BBA adds new section 138 of the Internal Revenue Code of 1986 containing Internal Revenue Service (IRS) rules concerning M+C MSAs. In general, an M+C MSA is a tax-exempt trust created solely for the purpose of paying the qualified medical expenses of the account holder. The account may be established only in connection with an M+C MSA plan, and must consist only of contributions from HCFA under the M+C program or of

transfers from another M+C MSA, if an enrollee has set up more than one M+C MSA. Section 138 also sets forth IRS rules concerning the distribution of MSA funds and tax penalties associated with the distribution of funds from an M+C MSA for purposes other than paying the qualified medical expenses of the account holder. (These provisions are discussed below in section III.J of this preamble.)

In establishing the M+C MSA option, Congress specified under section 1851(b)(4) of the Act that the opportunity to enroll in an M+C MSA plan was available on a demonstration basis to up to 390,000 enrollees through December 31, 2002. The Secretary is charged with regularly evaluating the impact of permitting enrollment in M+C MSA plans and with submitting a report to Congress by March 1, 2002, concerning the effects of the M+C MSA program and whether it should be extended beyond 2002.

The introduction of M+C MSAs builds upon the private market MSA demonstration program now available to small employers and the self-employed under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Like the HIPAA demonstration, the BBA conference report (H.R. 105–217, pg. 585) indicates that the introduction of M+C MSAs is premised on the need for beneficiaries to play a greater role in the health care purchasing decision. M+C MSAs offer beneficiaries incentives to ensure that the health care resources they need are allocated in an efficient manner. This increased consumer control is believed to have potential for discouraging the overutilization of health services.

In implementing the BBA provisions concerning the M+C MSA demonstration, our primary objective is to allow a true test of the potential benefits of the MSA concept to the Medicare program and its beneficiaries. Thus, as with other parts of the M+C regulations, an underlying design principle has been to preserve as much flexibility as possible for organizations and providers in terms of service delivery arrangements, while still building in the protections intended under the BBA for M+C MSA enrollees and the Medicare trust fund. For the convenience of the reader, all portions of the M+C regulations that specifically concern M+C MSA plans and accounts are discussed below in this preamble; however, the M+C MSA regulations do not constitute a separate subpart of new part 422. This is because, except as noted below, the general M+C requirements throughout part 422 apply equally to M+C organizations that offer M+C MSA plans; thus it would be redundant to repeat all applicable requirements in a separate M+C MSA subpart.

B. General Provisions (Subpart A)

Sections 422.2 and 422.4 set forth several definitions for terms connected with M+C MSA plans, including ''M+C MSA,'' ''M+C MSA plan,'' and ''MSA trustee.'' As noted in section II.D of this preamble, we also distinguish between a ''network'' and a ''non-network'' M+C MSA plan. The definitions consist of general meanings for these terms as used in the BBA and do not impose specific requirements. Thus, the definition for an MSA references the applicable requirements of sections 138 and 220 of the Internal Revenue Code, and the M+C MSA plan definition references the applicable requirements of new part 422.

The theory behind the new M+C MSA option is that a beneficiary will pay a lower monthly premium for a ''catastrophic'' insurance policy with a high deductible, and use the money deposited in his or her M+C MSA account to cover expenses during the extended period prior to this high deductible being reached. This concept is reinforced by the fact that Congress excluded from eligibility for M+C MSA plans individuals with ''first dollar'' health care coverage (such as, Medicaid-eligible individuals'—see discussion below), who would not be required to incur expenses during the significant period of time expected to transpire before the high M+C MSA plan deductible is met. This is also the reason that Congress amended the Medigap statute to preclude insurers from selling policies to enrollees in M+C MSA plans that would cover costs incurred before the high deductible is met. Indeed, the legislative history expressly refers to ''[p]rohibit[ing] the sale of certain [Medigap] policies to a person electing a *high deductible* plan,'' meaning an MSA plan. (H.R. Rep. No. 105–217, pg. 654 (1997). Emphasis added).

Although Congress did not include a minimum deductible amount, we believe that the statutory scheme, and the above-quoted reference to a ''high deductible plan'' in the Conference report, clearly *imply* that MSA plans would have a higher deductible than other plans. As noted above, we are seeking comment on providing for a minimum deductible based on the actuarial value of the average per capita cost-sharing under original Medicare rounded to the nearest $50. For 1999, this amount is $1,000. (Clearly, any deductible *lower* than the actuarial value of what original Medicare beneficiaries pay is *not* a ''high'' deductible.) We believe that a minimum deductible amount could ensure that M+C MSA plans comport with the ''high deductible'' design envisioned by Congress, without inappropriately limiting organizations' flexibility in designing M+C MSA plans. Without such a deductible, however, we are concerned that an organization could purport to offer an ''M+C network MSA plan'' that had such a low deductible that it would be impossible to distinguish from a coordinated care plan, although the plan would not be subject to the rules that Congress intended be applied to coordinated care plans. Therefore, in deciding whether to institute a minimum deductible for M+C MSA plans, we intend to examine any evidence that such abuses may be taking place, in addition to our review of public comments on the issue.

The only other general requirement concerning M+C MSA plans is the incorporation under § 422.4(a)(2) of the statutory provision (section 1851(a)(2)(B)) that one of the available alternatives under the M+C program is the combination of an M+C MSA plan with a contribution into an M+C MSA. Consistent with the statute, any State-licensed risk-bearing entity could offer an M+C MSA plan, whether it is an HMO offering an ''M+C network MSA plan'' under which beneficiaries are limited to a limited network of providers for covered services after the deductible is met, or an indemnity plan covering services on a fee-for-service basis after the deductible is met.

C. Eligibility, Election and Enrollment Rules (Subpart B)

1. Eligibility and Enrollment (§ 422.56)

Any individual who is entitled to Medicare under Part A, is enrolled under Part B, and is not otherwise prohibited (such as an ESRD patient), is eligible to enroll in an M+C plan. However, the statute places several limitations on eligibility to enroll in an M+C MSA plan. These limitations are set forth at § 422.56 of the regulations. Section 422.56(a) indicates that M+C MSA plans are established on a demonstration basis and incorporates the statutory provisions of section 1851(b)(4), that is:

- No more than 390,000 individuals may enroll in M+C MSA plans.
- No individual may enroll on or after January 1, 2003, unless the enrollment is a continuation of an enrollment already in effect as of that date.
- No individual may enroll or continue enrollment for any year unless

he or she can provide assurances of residing in the United States for at least 183 days during that year.

The 390,000 limit represents approximately 1 percent of the Medicare population. We do not intend to apply any State or regional limits on enrollment in M+C MSA plans, although we will monitor the number of enrollees on an ongoing basis. We believe it is unlikely that the number of applications for M+C MSAs will reach 390,000 in the first enrollment period, November, 1998. If necessary, however, we will accept applications for enrollment in M+C MSA plans on a first-come, first-served basis, with the first 390,000 applicants being allowed to enroll. We will notify organizations offering M+C MSA plans directly should the enrollment cap be reached.

The only restrictions on enrollment in M+C MSA plans under § 422.56(b) and (c) are those directly contemplated under section 1851(b)(2) and (3) of the statute. Specifically, § 422.56(b) states that an individual who is enrolled in a Federal Employee Health Benefits Program (FEHBP) plan, or is eligible for health care benefits through the Veterans Administration (VA) or the Department of Defense (DoD), may not enroll in an M+C MSA plan. The statute provides that the restriction on FEHBP enrollment may be eliminated if the Director of the Office of Management and Budget certifies to the Secretary that the Office of Personnel Management has adopted policies to ensure that the enrollment of FEHBP participants will not result in increased expenditures for health benefit plans. We intend to apply this same test for the enrollment restrictions that apply to VA and DoD-eligible individuals. In addition, § 422.56(c) incorporates the statutory prohibition under section 1851(b)(3) on enrollment in M+C MSA plans by individuals who are eligible for Medicare cost-sharing under Medicaid State plans.

Section 422.56(d) sets forth several additional restrictions on enrollment in M+C MSA plans that we believe are clearly consistent with statutory intent. These restrictions are discussed in detail below in section III.D.2 of this preamble, in the discussion of supplemental benefits under an M+C MSA plan.

2. Election (§ 422.62)

Section 1851(e) of the Act establishes general rules concerning the time periods when a beneficiary may elect to enroll in an M+C plan, with special rules for M+C MSA plans set forth at section 1851(e)(5). Based on these provisions, § 422.62(d) specifies that an individual may elect an MSA plan only during one of the following periods;

- An initial election period, that is, the 7-month period beginning 3 months before the individual is first entitled to parts A and B of Medicare.
- The annual coordinated election period in November of each year.

Unlike for other M+C plans, an individual may discontinue election of an M+C MSA plan only during the annual coordinated election period. Thus, effective January 1, 1999, enrollees in M+C MSA plans are ''locked in'' for 1 year, or for the remainder of the calendar year for elections during an initial election period that take effect other than on January 1. This lock-in rule contrasts sharply with the rules for other types of M+C plans, which provide for continuous open enrollment and disenrollment through December 31, 2001.

There are two exceptions to this lock-in rule. First, as specified under section 1851(e)(5)(C) and codified at § 422.62(d)(2)(ii), an individual who elects an M+C MSA plan during an annual election period in November of a given year, and has never before elected an M+C MSA plan, may revoke that election by submitting to the organization offering the plan a signed request or by filing the appropriate disenrollment form by December 15 of that year. In addition, we are providing at § 422.58(d)(2) that an individual may disenroll from an M+C MSA plan during the special election periods prompted by circumstances such as termination of the plan, change in the individual's place in residence, etc., as spelled out under § 422.62(b). As discussed in detail in section II.B of this preamble, section 1851(e)(4) provides that these special election periods are to take effect on January 1, 2002, in concert with the initial effective date for the lock-in rules for M+C plans other than MSA plans. Given that the lock-in rule for M+C MSA plans takes effect on January 1, 1999, we believe it is appropriate that the protections afforded by the special election period should be applicable at that time to individuals who elect M+C MSA plans.

3. Information About the M+C Program (§ 422.64)

Section 1851(d) and § 422.64 address the requirement that M+C organizations must provide the information that HCFA needs to help beneficiaries make informed decisions with respect to their available choices for Medicare coverage. The only M+C MSA-specific requirement involved here (also applicable for M+C private fee-for-service plans) is that the description of an M+C MSA plan's benefits should include differences in cost-sharing, premiums, and balance billing, as compared to other types of M+C plans (see § 422.64(c)(7)(iv)). We believe that the purpose of this requirement is to make sure that beneficiaries are aware of the fundamental differences between M+C MSA or private fee-for-service plans and other types of M+C plans, rather than to present detailed information concerning the benefits, premiums, and copayments for all other *specific* M+C plans in the area. For compliance purposes, then we intend to evaluate the information submitted by organizations for MSA plans in these terms. We note that we would apply the same standard in determining compliance with the requirement of § 422.110(b)(2)(ii) concerning an organization's responsibility to disclose to its enrollees a description of the benefits available under other types of plans.

D. Benefits (Subpart C)

1. Basic Benefits Under an M+C MSA Plan (§ 422.102)

Section 422.102 incorporates the statutory requirements for M+C MSA plans defined under section 1859(b)(3) of the Act, as outlined above. Thus, § 422.102(a) specifies that an MSA organization offering an MSA plan must make available to an enrollee, or provide reimbursement for, at least all Medicare-covered services (except for hospice services) after the enrollee's countable expenses reach the plan's annual deductible. We note that section 1859(b)(3)(A)(i) only uses the phrase ''provides reimbursement for'' the covered services, but the intent of the statute clearly includes situations where a network M+C MSA plan would either furnish the services directly or arrange for provision of the services. We believe that the phrase ''make available to the enrollee'' accounts for either of these situations.

Section 422.102(b) then indicates that countable expenses must include the lesser of actual costs or all the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation. In accordance with section 1859(b)(3)(A)(ii) of the statute, under each MSA plan, an organization would have the discretion to define what it considers countable expenses, subject to the statutory threshold of the Medicare

payable amount. We would envision that M+C organizations offering MSA plans could provide that countable expenses would include a considerably broader range of services than does Medicare, including expenses for services that often would constitute supplemental health care benefits under other M+C plans, such as prescription drugs, dental services, or preventative care services. (As discussed below, section 1852(a)(3)(B)(ii) prohibits an M+C MSA plan from providing most supplemental health care benefits before an individual reaches the annual deductible. However, counting the expenses for such services towards the annual deductible is permissible.) An M+C organization could also choose to provide that countable expenses under an M+C MSA plan would include a provider's full charges, rather than just the amount payable under the Medicare payment rate schedules.

Section 422.102(c) provides that after the deductible is met, an M+C MSA plan pays the lesser of 100 percent of either the actual expense of the services or of the amounts that would have been paid under original Medicare if the services were received by a Medicare beneficiary not enrolled in an M+C plan, including the amount that would have been paid by the beneficiary under his or her deductible and coinsurance obligation. As discussed below in section III.F., M+C balance billing protections do not apply in this situation. Thus, unless explicitly included in the terms of the M+C MSA plan, any amounts billed in excess of 100 percent of this Medicare allowed amount would be the responsibility of the enrollee. In this provision, we have interpreted the language in section 1859(b)(3)(A)(iii)(II) referring to the ''amounts that would be paid (without regard to any deductibles and coinsurance) under parts A and B'' to mean the amount that would be paid if there *were no* beneficiary liability provided for in the form of deductibles and coinsurance—in other words, the full amount of the Medicare rate. We have put this a different way in § 422.102(c), providing that the amount in question *includes* the amounts that the beneficiary would pay in deductibles and coinsurance. We considered interpreting ''without regard to any deductibles and coinsurance amounts'' to mean without *counting* the amounts original Medicare beneficiaries would pay in deductibles and coinsurance. We decided, however, that after a deductible of up to $6000, and with balance billing permitted, M+C MSA plans should be required to pay the full Medicare payment rate once the deductible is met. Again, an organization would be free to offer expanded benefits under an M+C MSA plan beyond the minimum requirements after the deductible is met, including supplemental benefits that it could not offer before the deductible is met.

Section 422.103(d), concerning the annual deductible, is based on section 1859(b)(3)(B). As the statute specifies, the maximum annual deductible for an MSA plan for contract year 1999 is $6,000. In subsequent contract years, the maximum deductible may not exceed the maximum deductible for the previous contract year increased by the national per capita M+C growth percentage for the year. In calculating the maximum deductible for future years, HCFA will round the amount to the nearest multiple of $50.

Another issue we examined in developing the regulations concerning the annual deductible for M+C MSA plans was whether to establish specific requirements on deductibles for individuals who enroll in M+C MSA plans effective other than on January 1 of a given year, that is, individuals who turn 65 and make midyear elections of an M+C MSA plan within their initial enrollment periods. Our primary alternatives on this issue were to: (1) require all M+C MSA plans to ''prorate'' the deductible, that is, reduce the amount of the deductible for midyear enrollees in proportion to the amount of the calendar year remaining or (2) allow insurers the flexibility to decide for themselves how to deal with partial year enrollees. Although the prorating alternative would reduce the cost-sharing burden on beneficiaries during the first partial year, and thus possibly make it more likely that an individual whose initial election period occurs late in the year would choose an M+C MSA plan, this option has several drawbacks. Few if any insurance carriers now prorate their deductibles for midyear enrollees, and we are reluctant to implement such an approach unilaterally, particularly since we have no evidence that the costs of implementing a prorated system would be exceeded by the benefits to beneficiaries in terms of reduced risk. Such a requirement could limit interest in establishing M+C MSA plans, if insurers believed that they could be placed at risk of the enrollment of individuals with low prorated deductibles who anticipate high cost short-term health care needs.

Instead, we decided to allow insurers to decide for their M+C MSA plans how to deal with partial year enrollees. This should foster flexible approaches to this situation, with organizations making decisions based on their perceptions of the cost of implementation and the benefits to them in terms of attracting prospective enrollees. For example, an organization's plans could include a ''carry-over'' procedure. Under such a procedure, bills incurred during a specified period of one calendar year could be carried over to the following year and applied to the next year's deductible.

2. Supplemental Benefits (§§ 422.102 and 422.103)

Section 422.102 addresses the general M+C rules on supplemental benefits. Unlike other M+C plans, MSA plans are not permitted to include any mandatory supplemental benefits and are limited in terms of the optional supplementary benefits that can be offered. In accordance with section 1852(a)(3)(B)(ii), § 422.103(a) specifies that an M+C MSA plan generally may not provide supplemental benefits that cover expenses that count toward the annual deductible. In addition, section 4003(b) of the BBA added new section 1882 to the Act to prohibit the sale of most supplementary health insurance policies to individuals enrolled in M+C MSA plans. The only exceptions to this rule are spelled out in section 1882(u)(2)(B). These exceptions apply both for purposes of the prohibition on selling freestanding supplementary health insurance (or ''Medigap'' insurance), and for purposes of ''optional supplemental benefits'' offered under M+C MSA plans. These exceptions are reflected in § 422.103(a)(2). Under § 422.103(a)(2), the only types of policies that an enrollee in an M+C MSA plan may purchase that cover expenses that may count toward the annual deductible are as follows:

- A policy that provides coverage for accidents, disability, dental care, vision care, or long-term care.
- A policy in which substantially all coverage relates to liabilities incurred under workers' compensation laws, tort liabilities, or liabilities relating to use or ownership of property.
- A policy that provides coverage for a specified disease or illness or pays a fixed amount per day (or other period) for hospitalization. (Note that the fact that an organization offering an M+C MSA plan permits a particular expense to count toward the plan's annual deductible does not necessarily mean that such expenses are considered ''qualified medical expenses'' by the IRS.)

The above restrictions on optional supplemental benefits and Medigap

coverage under section 1882, combined with Congress' explicit exclusion of individuals with ''first dollar'' health coverage under government programs (Medicaid, VA benefits, and FEHBP benefits—see section 1851(b)(2) and (3) and discussion above), make it clear that Congress intended that individuals enrolled in M+C MSA plans would be required to use the money in their M+C MSA accounts to pay for services until the ''high deductible'' under the plan is met. While Congress addressed government programs under which expenses during the deductible would be covered, and prohibited the *sale* of *new* private supplemental insurance that would cover such deductible amounts (whether an optional supplemental benefit offered under an M+C MSA plan, or a freestanding ''Medigap'' policy), some categories of individuals with first dollar coverage that would cover expenses that would count toward an M+C MSA plan deductible would remain eligible to enroll in M+C MSA plans absent a regulatory prohibition.

We believe that it would give effect to clear congressional intent to expand the categories of individuals ineligible to enroll in M+C MSA plans to include the additional categories that Congress neglected to include. For example, while Congress prohibited the *sale* of private insurance covering expenses that count toward an M+C MSA deductible, it did not address individuals who may already *have* such coverage, including those who have first dollar Medigap coverage through their employer. In addition, individuals who have elected hospice coverage are also eligible for first dollar Medicare payment, without any qualification in the case of MSA plans. (See section 1853(h)(2)(A).) This is also inconsistent with Congress' intended design for the M+C MSA option. Pursuant to our authority under section 1856(b)(1) to establish M+C standards by regulation, we accordingly are providing in § 422.56(d) that individuals with such health benefits are ineligible to elect an MSA plan.

As mentioned above, M+C MSA plans may not provide any supplemental benefits, except those exempted, covering expenses that count towards the annual deductible. Once the deductible is reached, however, there are no limitations on the supplemental benefits a plan may offer, as long as the plan satisfies the requirements concerning making available basic part A and B Medicare services. We believe that a market may emerge for supplemental insurance policies in connection with M+C MSA high deductible insurance policies. We considered the possibility of establishing one or more sample benefit plans for use in conjunction with M+C MSA plans, similar to the limited number of standardized Medigap plans that are now offered. Although we are not doing so at this time, we welcome comments on the need for such uniform plans.

E. Quality Assurance (Subpart D)

Like for other M+C plans, an organization offering an MSA plan must have an ongoing quality assessment and performance improvement program for the services furnished to M+C enrollees under the plan. As discussed in detail above, the quality assurance requirements that apply to an M+C MSA plan depend on whether the plan is a network model plan, that is, a plan that provides benefits either through contracting providers or under arrangements made by the plan, or a non-network plan. Consistent with section 1852(e)(2) of the Act, a network model M+C MSA plan must meet requirements similar to those that apply to all other M+C coordinated care plans (with the exception of the achievement of minimum performance levels); the statute and regulations establish different requirements for non-network M+C MSA plans. See section II.D of this preamble, and § 422.152 of the regulations, for more information on this subject. Also, see section II.D. of the preamble and § 422.154 for information on the external review requirements that apply to network M+C MSA plans. Under § 422.154(b)(1), the external review requirements do not apply to non-network M+C MSA plans.

F. Relationships Between Plans and Participating Physicians (Subpart E)

For the most part, subpart E of new part 422 does not establish any requirements that are specific to MSA plans. However, § 422.214, ''Special rules for services furnished by noncontract providers,'' does have implications for enrollees in MSA plans. The provisions of this section are based on section 1852(k) of the Act, beginning with the requirement under section 1852(k)(1) that for enrollees in M+C coordinated care plans, a physician that does not have a contract with the plan must accept as payment in full an amount no greater than the amount the physician could collect if the individual were under the fee-for-service Medicare program, including any applicable deductibles, coinsurance, or balance billing permitted by the plan. (See section 1848(g) concerning the Medicare fee-for-service rules on limiting charges.) Section 1852(k)(2) then establishes balance billing limits for M+C private fee-for-service plans, as discussed in detail in section IV of this preamble and § 422.216; however, the statute contains no balance billing protections for enrollees in M+C MSA plans.

It is clear from the legislative history of the provisions imposing balance billing limits that the omission of any limits under M+C MSA plans was not inadvertent. Page 609 of the Conference Report (H.R. Rep. No. 105–217) refers to the House bill, which included across the board limits on what could be collected. The Senate amendment is described as including a ''[similar provision except that it *excepts from the requirement* * * * a[ ] fee-for-service plan as well as *an MSA plan*.'' The ''conference agreement'' is then described as ''including] the Senate provision with an amendment to provide for application of the provision to Medicare+Choice *fee for service plans*. * * *'' Thus, Congress clearly indicates that it provided for a balance billing limit for M+C coordinated care plans and private fee-for-service plans (albeit a different limit), but *not* for M+C MSA plans. On page 611, the Conference Report expressly states that the House bill provided that an ''MSA plan * * * would not be subject to the * * * limitations on balance billing.'' The conference agreement indicates that it ''includes'' this ''House bill'' position. In light of the absence of any statutory provision for a limit on balance billing under M+C MSA plans, and these clear statements of congressional intent that there be no such limits, we have not provided for any limits on balance billing under M+C MSA plans in these regulations.

G. Payments Under MSA Plans (Subpart F)

Section 1853 describes the method to be used to calculate the annual M+C capitation rate for a given payment area (see section II.F of this preamble and § 422.254). We apply the same methodology in determining the annual capitated rate associated with each M+C MSA plan enrollee. Thus, for calendar year 1999, the capitated rate will continue to be adjusted for the age, gender, Medicaid-eligibility, disability, institutional status, and employment of the individual beneficiary, with risk adjustment scheduled to begin on January 1, 2000, as also discussed in detail in section II.F of this preamble.

The special rules concerning the allocation of the M+C capitated amount for individuals enrolled in M+C MSA plans are set forth at section 1853. In

general, HCFA will allocate the capitated amount associated with each M+C MSA enrollee as follows:

- On a lump-sum basis at the beginning of the calendar year, pay into a beneficiary's M+C MSA an amount equal to the difference between the annual M+C capitation rate for the county in which the beneficiary resides and the M+C MSA premium filed by the organization offering the MSA plan (this premium is uniform for all enrollees under a single M+C MSA plan.) This results in a uniform amount being deposited in an M+C MSA plan enrollee's M+C medical savings account(s) in a given county, since the uniform premium amount will be subtracted from the uniform county-wide capitation rate for every enrollee in that county.
- On a monthly basis, pay to the M+C organization an amount equal to one-twelfth of the difference, either positive or negative, between the annual M+C capitation payment for the individual and the amount deposited in the individual's M+C MSA.

Section 422.262 contains the regulations concerning the allocation of Medicare trust funds for enrollees in M+C MSA plans. First, under § 422.262(a), an enrollee must establish an M+C MSA with a qualified trustee or custodian. An enrollee may establish more than one account, consistent with section 1853(e)(2)(B) of the Act, but must designate the particular account to which payments by HCFA are to be made. As specified under § 422.262(b), a trustee can be a bank, insurance company, or anyone approved by the IRS to be a trustee of Individual Retirement Accounts. Section 422.262(b) also requires that M+C MSA trustees must register with HCFA, agree to comply with IRS rules concerning MSAs, and provide organizational information that HCFA may require.

The specific requirements concerning the amount that HCFA pays into an individual's M+C MSA are spelled out at § 422.262(c). We calculate the payment by first comparing the monthly premium for the M+C MSA plan to the county-wide capitation rate under § 422.252 that is used in making payments to M+C organizations under other types of M+C plans (final payment to M+C organizations is based on this county-wide capitation rate, adjusted by demographic factors). If the monthly premium is less than the monthly capitation rate for the county, HCFA deposits into the individual's M+C MSA a lump sum equal to the annual difference between these two amounts, that is, the monthly difference multiplied by 12, or by the number of months remaining in the calendar year when the individual becomes covered under the M+C MSA plan.

The lump-sum payment is made in the first month of coverage under the M+C MSA plan, but HCFA makes no payment until the individual has not established an M+C MSA before the beginning of the month. Should an individual's coverage under an M+C MSA plan end before the end of a calendar year, HCFA will recover the excess portion of the lump-sum deposit attributable to the remaining months of that year.

In summary, Medicare's contributions to an individual's M+C MSA are equal to the difference between the unadjusted county-wide capitation rate for the county in which the enrollee lives and the premium filed by the individual's high deductible M+C MSA plan. For example, if the annual Medicare payment rate for a county is $6,000 ($500 per month), and the annual premium for an M+C MSA insurance plan is $4800 ($400 multiplied by 12), HCFA would deposit $1,200, in January, into the M+C MSA of each plan enrollee residing in that county. It would pay to the insurer (generally divided into 12 equal monthly payments) the difference between the demographically adjusted M+C payment amount for that individual and the MSA contribution. (See the example below.) The annual payment by HCFA represents the only permissible deposit into the individuals's M+C MSA, with the exceptions of transfers from another M+C MSA established by the same individual or interest or income that accrues to the account.

Example of Payments Under an M+C MSA Plan

Monthly premium for an M+C MSA plan	$400
Monthly M+C county-wide capitation rate	500
Monthly demographically adjusted M+C payment for an individual beneficiary:	
Individual A (65-year old beneficiary)	450
Individual B (85-year old beneficiary)	700

A. Annual contribution to enrollee's M+C MSA =
(M+C county-wide capitation rate − M+C MSA plan monthly premium) × 12. ($500 − $400) × 12 = $1,200

B. Monthly payment to an M+C organization under an M+C MSA plan for an enrollee =
Demographically adjusted M+C payment rate for an enrollee − Monthly contribution to the enrollee's M+C MSA plan
Individual A: $450 − $100 = $300
Individual B: $700 − $100 = $600

In theory, payments to the plan for an individual enrollee could be positive or negative, depending on the relationship between a plan's premium and the capitation rate for a given county. If, in the example above, the M+C MSA plan premium were only $25 (rather than $400), the monthly contribution to an enrollee's M+C MSA would be $475 ($500 − $25 = $475). For the 65-year old beneficiary (Individual A), the resultant payment to the plan would be a negative $25 ($450 − $475 = (−$25)). Given that organizations offering M+C MSA plans likely will carefully assess payment ranges and demographic factors within their market areas before proposing a premium, we believe that a negative payment would be rare, but not impossible.)

H. Premiums (Subpart G)

Section 1854 establishes the requirements for determination of the premiums charged to enrollees by M+C organizations. Like other M+C organizations, organizations offering M+C MSA plans in general must submit by May 1 of each year information concerning enrollment capacity and premiums. For M+C MSA plans, the information to be submitted includes the monthly M+C MSA plan premium for basic benefits and the amount of any beneficiary premium for supplementary benefits. These requirements are set forth under section 1854(a)(3) of the act and § 422.306(c) of the regulations.

Unlike for M+C coordinated care plans, section 1854(a)(5) Act expressly exempts M+C MSA plan premiums from review and approval by the Secretary. Section 1854(b)(1)(B) merely states that for M+C MSA plans, the monthly amount of the premium charged to an enrollee equals the M+C monthly supplemental beneficiary premium, if any. Although this provision effectively

precludes an organization offering an M+C MSA plan from charging an additional premium to an enrollee for basic Medicare benefits paid for through the capitated payment made by HCFA, the plan is free to set the basic and supplemental premium at whatever levels the market place will bear.

The only statutory limitation placed on an M+C MSA plan's ability to establish premiums is the ''uniform premium'' requirement of section 1854(c). The effect of this provision is that the monthly basic and supplementary premiums may not vary among individuals enrolled in an M+C MSA plan. (See the discussion of service area in section II.A. of this preamble.) Thus, insurers that want to charge different amounts for different benefits, according to geographic areas for example, could do so only by establishing multiple M+C MSA plans. Within a plan, however, payments into the M+C MSAs of individuals residing in the same county will be uniform; payments to the plans will vary for each individual.

I. Other M+C Requirements

The remaining requirements under subpart 422 have few if any implications specific to M+C MSA plans. For example, the organizational and financial requirements, provisions on compliance with State law, contracting rules, and grievance and appeal requirements generally apply in equal measure to MSA plans as to other types of plans. More accurately, perhaps, these requirements primarily apply to the M+C organization, rather than the plan; thus, an organization offering any type of M+C plan must meet the applicable requirements.

One issue that may require clarification, however, involves the provision of section 1856(b)(3)(B)(i) (and § 422.402(b)) that any State standards relating to benefit requirements are superseded. We recognize that this provision means that State benefit rules will not apply (such as State laws that mandate first dollar coverage for particular benefits such as mammograms or other preventative services). Some States may not license entities to offer catastrophic coverage, and it is possible that M+C MSA plans could not be offered in that State. We welcome public comment on this issue.

The only other sections of these regulations that contain requirements that are specific to M+C MSA plans are found in Subpart K—Contracts with M+C Organizations. First, in accordance with section 1857(c)(3), § 422.504(a) specifies that the effective date for a contract providing coverage under an M+C MSA plan may be no earlier than January 1, 1999.

We note that § 422.500(b)(2) authorizes HCFA to include in a contract any requirements that we find ''necessary and appropriate'' that are not inconsistent with the M+C statute and regulations. Given the demonstration basis of M+C MSA plans under section 1851(b)(4), and the corollary requirements for an evaluation and a report to Congress, we believe it may be necessary and appropriate to require that organizations offering M+C MSA plans provide HCFA with data that will enable us to evaluate M+C MSA plans in terms of selection, use of preventive care, access, and impact on the Medicare trust fund. We are now in the process of determining what, if any, specific data will be required with respect to M+C MSA plans (beyond the encounter data to be collected with respect to all M+C plans) to facilitate HCFA's evaluation. In § 422.502(f)(2)(vii), we provide authority for HCFA to request data from M+C organizations offering MSA plans related to selection, use of preventive care, and access to services.

J. Tax Rules

As mentioned earlier, section 4006 of the BBA added new section 138 to the Internal Revenue Code (IRC) of 1986 concerning M+C MSAs. The regulations set forth in this interim final rule do not incorporate the IRC provisions on M+C MSAs. However, for the convenience of the reader, we are presenting here a brief summary of the tax rules associated with M+C MSAs. For a full explanation of the tax consequences of establishing a M+C MSA, we refer readers to sections 138 and 220 of the IRC and to the relevant IRS publications. (For more information, contact the IRS at (888) 477–2778 or through its website at www.irs.ustreas.gov.)

When an individual joins an M+C MSA plan, HCFA makes a specified contribution, as explained above, into the M+C MSA designated by the individual. No other contribution may be made into the M+C MSA, and the contribution is not included in the taxable income of the account holder. Any income earned on amounts held in the M+C MSA are not currently included in taxable income, similar to an individual retirement account.

Withdrawals from an M+C MSA are not considered taxable income if used for the ''qualified medical expenses'' of the account holder, regardless of whether the account holder is still enrolled in an M+C MSA plan at the time of the distribution. In general, ''qualified medical expenses'' are defined the same as under the IRS rules relating to itemized deductions for medical expenses. (See sections 213(d) and 220(d)(2)(A) of the IRC and IRS publication 502, Medical and Dental Expenses.) For M+C MSA purposes, however, most health-related insurance premiums do not constitute qualified medical expenses, nor do amounts paid for the medical expenses of any individual other than the account holder. Also, keep in mind that the IRS definition of qualified medical expenses encompasses a broader range of items and services than are covered by Medicare, including for example prescription drugs and dental services. Thus, items that are considered qualified medical expenses by the IRS do not necessarily constitute countable expenses toward an M+C MSA plan's annual deductible.

An enrollee in an M+C MSA plan may make withdrawals from an M+C MSA that are not used to pay for the qualified medical expenses of the account holder, but these withdrawals are included in the account holder's taxable income and may be subject to additional tax penalties under section 138(c)(2) of the IRC. The additional tax provisions do not apply to distributions following the disability (as defined in section 72(m)(7) of the IRC) or death of the account holder. Finally, under section 138(d) of the IRC a surviving spouse of an M+C MSA holder may continue the M+C MSA upon the death of the account holder, including making nontaxable withdrawals for the qualified medical expenses of the spouse or the spouse's dependents, but may not make new contributions to the M+C MSA. Again, we recommend contacting the IRS for further details.

K. Letters of Intent

In closing, we wish to solicit letters of intent from organizations that intend to offer high deductible M+C MSA insurance plans to Medicare beneficiaries and/or to serve as M+C MSA trustees or custodians. A letter of intent to offer an M+C MSA plan should include basic information about the plan, the geographic area in which the plan intends to operate, the name, address, and telephone number of a contact person, so that beneficiaries can call the plan to verify whether the plan did, in fact, submit an application and receive our approval. This letter of intent must be received no later than July 31, 1998.

For prospective M+C MSA trustees, the letter of intent must include the name of the organization, the address, a contact person and telephone number,

funds routing number, Federal tax identification number, the geographic area the trustee will serve, a public information number for publication, and attestation that the organization is a chartered bank, licensed insurance company, or other entity qualified under section 408(a)(2) or section 408(h) of the Internal Revenue Code to act as a trustee or custodian of an individual retirement account. For trustees, no further application to us will be required if the organization appears to be qualified based upon submitted information. Trustees that decide at a later date to participate will have to notify us before offering M+C MSAs.

Statements of intent should be submitted to—Health Care Financing Administration, CHPP, Attn: Cynthia Mason, Room C4–17–27, 7500 Security Boulevard, Baltimore, Maryland 21244.

A letter of intent in no way commits an organization to submit an application to offer an M+C MSA plan or serve as an M+C MSA trustee, nor does it preclude the submission of an application if a letter of intent is not submitted to us. As part of our information campaign, we plan to publish and disseminate the information we receive to inform beneficiaries of the plans that may be participating in the M+C MSA plan demonstration project.

IV. M+C Private Fee-for-Service Plans

1. Background and Definition of M+C Private Fee for Service Plans (§ 422.4(a)(3))

As noted above, among the type of M+C options available under section 1851(a)(2) is an M+C private fee for service plan. An M+C private fee for service plan is an M+C plan like any other except where there are special rules and exceptions that apply to them. The effect of these special rules and exceptions is that we believe that M+C plans will function much like a traditional health insurance plan rather than a coordinated care plan nor a medical savings account. The law provides considerable flexibility in the creation of this M+C option and therefore, it is likely that M+C private fee for service plans will vary widely in how they function. Moreover, the law does not limit the premiums that an M+C organization may charge for an M+C private fee for service plan, thus making it very sensitive to market forces in its pricing, its benefits and its function.

We propose to define an M+C private fee-for-service plan as being an M+C plan that pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk, does not vary the rates for a provider based on the utilization of that provider's services, and does not restrict enrollees' choice among providers who are lawfully authorized to provide the services and agree to accept the plan's terms and conditions of payment. This is the statutory definition of M+C private fee-for-service plan at 1859(b)(2)(A). The requirements these plans must meet to contract with HCFA as an M+C private fee-for-service plan are incorporated into the relevant sections of this regulation. An M+C private fee-for-service plan must meet all of the requirements for any other M+C plan, except to the extent that there are special rules for M+C private fee-for-service plans.

2. Quality Assurance (§§ 422.152 and 422.154)

The law exempts M+C private fee for service plans and non-network MSAs from some of the quality assurance requirements of the law. Moreover, the law exempts M+C private fee for service plans and non-network MSAs from external quality review if they do not have written utilization review protocols. Specific discussion of the statute and the regulations that implement these provisions that apply to both M+C private fee for service plans and non-network MSAs are found in subpart D at sections 422.152 and 422.154. As with all other requirements for M+C organizations and M+C plans, those provisions of regulations that are not specific to coordinated care plans and MSAs also apply to M+C private fee for service plans.

3. Access to Services (§ 422.214)

In § 422.214 we implement the special requirements for access to health services that are contained in section 1852(d)(4). The law requires that the Secretary must assure that the M+C private fee-for-service plan offers sufficient access to health care. Specifically, in § 422.114(a) we require that an M+C organization that offers an M+C private fee-for-service plan must demonstrate to HCFA that it has sufficient number and range of health care providers willing to furnish services under the plan. Pursuant to the specific instructions of the law, under § 422.114(a) HCFA will find that an M+C organization meets this requirement if, with respect to a particular category of provider, the plan has—

- Payment rates that are not less than the rates that apply under original Medicare for the provider in question;
- Contracts or agreements with a sufficient number and range of providers to furnish the services covered under the plan; or
- A combination of the above.

Hence, an M+C private fee-for-service plan will be found to have met the access requirements for a category of services if it has sufficient numbers of providers under direct contract in its service area or, if not, it has payment rates that are equal to or higher than the original Medicare payment for the service. This access test must be met for each category of service established by HCFA on the M+C organization application. Clearly, if an M+C private fee-for-service plan has payment rates that are no lower than Medicare, it need not address if it has a sufficient number of providers of services. However, where the plan has payment rates that are less than the Medicare payment for that type of provider, the plan must demonstrate that it has sufficient number of providers of that type under direct contract. For purposes of making this judgement of sufficiency, HCFA will use the same standards for M+C private fee-for-service plans as for coordinated care plans. We see no basis to use different standards.

In § 422.114(b) we specify that the plan must permit the enrollees to receive services from any provider that is authorized to provide the service under original Medicare. This implements that part of section 1852(d)(4) that says that the access requirements cannot be construed as restricting the persons from whom enrollees of the M+C private fee-for-service plan may obtain covered services.

4. Physician Incentive Plans (§§ 422.208 and 422.210)

In § 422.208(e) we specify that an M+C private fee-for-service plan may not use capitated payment, bonuses, or withholds in the establishment of the terms and conditions of payment. This is necessary to implement that part of the definition of an M+C private fee-for-service plan that specifies that the plan must pay without placing the provider at financial risk. We believe that these physician incentives place the physician at financial risk and thus are not permitted by the law for M+C private fee-for-service plan payments. Capitation places physicians at risk because of the uncertainty of the extent to which the beneficiary will require the physician's time and services to provide an adequate level of service. Withholds from payment place the physicians at financial risk because of the uncertainty of what the ultimate payment for the

services furnished will be. Bonuses are essentially the same as withholds. In both the case of bonuses and withholds, the physicians knows the least amount that could be paid but in both cases, they face uncertainty about what the total payment from the plan would be for the services furnished.

5. Special Rules for M+C Private Fee-for-Service Plans (§ 422.216)

In § 422.216(a) we address payment to providers. Specifically in 422.216(a)(1) we state that the M+C organization offering an M+C private-fee-for-service plan pays contract providers (including those that are deemed to have contract under § 422.216(f)) on a fee-for-service basis at a rate, determined under the plan, that does not place the provider at financial risk. This reflects the statutory definition of an M+C private fee-for-service plan.

We also specify in § 422.216(a)(1) that the payment rate includes any deductibles, coinsurance, and copayment imposed under the plan and must be the same for all providers paid pursuant to a contract whether or not the contract is signed or deemed to be in place as discussed below. This reflects our understanding of the meaning and use of these terms in common insurance use. It also reflects our belief that the plan rate (on which balance billing discussed below is based) is intended to be analogous to the Medicare allowed amount for a service, of which the deductible, coinsurance or copayment is a part. We think the deductible, and coinsurance or copayment is a part of the plan payment rate because deductibles have to be subtracted from that plan payment and because coinsurance is a percentage of the plan payment rate, thus being included within the rate by definition. We believe that the payment rate does not include balance billing because the common definition of balance billing under both original Medicare and common insurance is an amount above and beyond the payment rate established for the service. Balance billing is discussed in more detail below in (c) as a provider charge to enrollees.

As noted above, we specify in § 422.216(a)(1)(i) that a uniform payment rate must be established for a given item or service furnished under a contract, whether the contract is signed or deemed to exist (*see* discussion of deemed contracts below). In § 422.216(b)(1)(i), we also require that the plan deductible, coinsurance or copayments and other beneficiary liability be uniform for services furnished by all contracting providers, whether contracts are signed or deemed to be in place. These two requirements are closely related, since permissible enrollee liability is linked by statute to the plan's payment rate. The balance billing limitation in section 1852(k)(2)(A) that applies to M+C private fee-for-service plans is based on the plan payment rate, which has deductible, copayment and coinsurance amounts built into it. In our view, therefore, the uniform cost-sharing rule in § 422.216(b)(1)(i) follows from the uniform payment rate rule in § 422.216(a)(1)(i).

We believe that the uniform rate requirement in § 422.216(a)(1)(i) is implicit in the definition of private fee-for-service plans in section 1859(b)(2), which refers in the singular to reimbursing, hospitals physicians and other providers at ''a rate'' determined under the plan. The balance billing limit in section 1852(k)(2)(A) even more explicitly supports a uniformity rule, in referring in the singular to ''a'' prepayment ''rate'' that is established under ''a contract (including [a deemed contract]). * * *'' Section 1852(k)(2)(A) thus makes clear that Congress contemplated that a *single* ''rate'' would be established for a given service, or for a service in a given area, under ''a contract,'' and that this rate would apply under the contract, ''including'' a contract deemed ''through the operation of subsection (j)(6)'' of section 1852 (discussed below).

Even if the statute did not refer to a single rate that applies under a contract, and expressly include a deemed contract in this statement, we would exercise our authority under section 1852(b)(1) to impose a uniform rate and cost-sharing requirement. We understand from oral presentations and written comments received in response to the January 20, 1998 **Federal Register** notice (63 FR 2920), that some entities would like to establish different payment rates and enrollee cost-sharing for providers that sign contracts than those which would apply to providers deemed to have a contract. These entities indicated that they wanted to establish incentives to use the network of providers with signed contracts. We believe that it would be inconsistent with the scheme established by Congress to permit this.

Under such an approach, the M+C organization would in essence be establishing a defined and limited network of preferred providers. Congress has applied a different set of rules to plans that employ provider networks, and exempted M+C private fee-for-service plans from these requirements. Indeed, a ''preferred provider organization'' (PPO) plan and ''point of service'' option are each expressly mentioned as examples of ''coordinated care plans'' subject to the quality assurance rules that apply to network plans, including network MSA plans. We believe that permitting private fee-for-service plans to have different cost-sharing amounts for providers with signed contracts would create a ''loophole'' permitting organizations from offering network type PPO plans without complying with the quality assurance requirement that Congress intended to apply to network plans.

In § 422.216(a)(1)(ii) we specify that contracting providers must be paid on a fee-for-service basis. This is required by the definition of M+C private fee-for-service plans contained in 1859(b)(2)(A).

In § 422.216(a)(1)(iii) we specify that the M+C organization must make the payment rate available to providers that furnish items or services that may be covered under the M+C private fee-for-service plan offered by the organization. We require this to ensure that the contracting providers will be advised or be able to acquire the amount of payment for the services they furnish to plan enrollees. This is particularly important given the plan's flexibility to set and change payment rates.

In § 422.216(a)(2) we specify that the M+C organization must pay a contract provider (including one deemed to have a contract) an amount that is equal to the payment rate described above less any applicable deductible, coinsurance or copayment. The M+C plan's share of the payment is the payment rate (which includes deductible, coinsurance and copayment as discussed above) less that enrollee's cost-sharing.

In § 422.216(a)(3) we also specify that the plan pays for services of noncontract providers in accordance with § 422.100(b)(2).

Section 1852(k)(2)(B)(i) specifies that the minimum payment rate for noncontracting providers of M+C private fee-for-service plans must be the payment rate set in 1852(a)(2)(A), the same payment rate that applies when coordinated care plans pay noncontracting providers for approved services. The provisions of 1852(a)(2)(A) are set in regulations at § 422.100(b)(2) and thus that provision applies to the payment to noncontracting providers by M+C private fee-for-service plans. Thus, the plan must pay the provider at least the amount that the provider would have received under original Medicare, including any allowed balance billing amounts. The provider must accept this amount, together with allowable cost

sharing paid by the enrollee, as payment in full.

In § 422.216(b) we address provider charges to enrollees. Specifically in § 422.216(b)(1) we state that a contract provider (including one that is deemed to have a contract under paragraph (f) (discussed below) may charge the enrollee no more than the deductible, coinsurance, copayment, and balance billing amounts permitted under the plan, that the plan must have the same cost-sharing for deemed contract providers as for contract providers and that the plan may permit balance billing no greater than 15 percent of the payment rate for the service.

The provisions regarding what enrollees may be charged are based on our interpretation of section 1852(k)(2)(A)(i) that says that a provider shall accept as payment in full ''* * * an amount not to exceed (including any deductibles, coinsurance, copayments, or balance billing otherwise permitted under the plan) an amount equal to 115 percent of such payment rate.'' We believe that the intent of this provision is that the plan may, but is not required to, permit the provider to collect balance billing equal to but not in excess of 15 percent of the plan payment rate. We believe that the intent of the section was to permit a balance billing provision that mirrors that which currently exists section 1848(g) with respect to services paid under the Medicare fee schedule for physician services for beneficiaries who are enrolled in original Medicare.

We recognize, however, that the inclusion of the words ''balance billing otherwise permitted under the plan'' in the second parentheses in section 1852(k)(2)(A)(i) could be construed, if read literally, to permit the 115 percent limit on enrollee liability for balance billing to be applied to a payment ''rate'' that already included balance billing ''otherwise provided for'' in the plan.

This interpretation would in effect have created two balance billing amounts: one balance billing amount within the payment rate (that would be above and beyond the deductible, coinsurance and copayment) and another balance billing amount based upon the payment rate (effectively a balance billing amount as a percentage of another balance billing amount). This is a convoluted result that we do not believe was intended. In addition to producing a convoluted result, the above reading of the reference to balance billing in the second parenthetical in section 1852(k)(2)(A)(i) would permit M+C organizations to avoid the limitation on enrollee liability in section 1854(e)(4), which applies only to deductibles, coinsurance, and copayments. *See* section G. below. If an M+C organization offering a private fee-for-service plan could ''provide for'' balance billing amounts in its payment rate, such amounts would not count towards the overall limit on enrollee liability in section 1854(e)(4). This could result in unlimited enrollee liability if such unlimited ''plan'' balance billing amounts were coupled with balance billing of 115 percent of rates that include the plan balance billing.

The provision that requires that the plan establish the same cost-sharing for the services of deemed contract providers as for contract providers is discussed above in its relationship to § 422.216(a)(1).

In § 422.216(b)(1)(iii) we specify that the M+C organization must specify in the contract the deductible, coinsurance, copayment, and balance billing permitted under the plan for services furnished by a contracting provider (including a deemed contract under paragraph (f)). We believe it is important to ensure that the providers who furnish services are explicitly aware of the amounts they can collect from enrollees since there are potential penalties for violation of these limits.

In § 422.216(b)(1)(iv) we specify that an M+C organization is subject to intermediate sanctions under § 422.752(a)(7), under the rules in subpart O of part 422, for failing to enforce limits on beneficiary liability that apply to contract (including deemed contract) providers. This implements section 1852(k)(2)(A)(i).

In § 422.216(b)(2) we specify that a noncontract provider may charge the enrollee no more than the cost-sharing established under the M+C private fee-for-service plan limited as specified in § 422.308(b). This requirement implements section 1852(a)(2), which applies to all M+C plans other than MSA plans, and which is referenced in section 1852(k)(2)(B)(i), which applies specifically to payments to non-contract providers under M+C private fee-for-service plans. Section 1852(a)(2) requires that M+C organizations provide for payment to non-contracting providers of an amount, representing the sum of payment from the organization and any cost-sharing provided for under the M+C plan, that is at least equal to the total dollar amount of payment that would be authorized to be paid under parts A and B, including any balance billing permitted under such parts. We have defined ''cost-sharing'' in section 422.2 as including only deductibles, copayments and coinsurance, and not balance billing amounts. Because section 1852(a)(2)(A)(i) uses the term cost-sharing, we believe that it requires that M+C organizations make payment in an amount that, when combined with deductible amounts, coinsurance or copayments provided for under the M+C plan, at least equals the amount the individual or entity would be able to collect under original Medicare, as we have provided in section § 422.216(b)(3). This means that enrollees must be held harmless against any balance billing by non-contracting providers.

While § 1852(a)(2) thus limits enrollee liability to deductible, coinsurance, and copayment amounts (and does not permit enrollee liability for balance billing in the case of non-contracting individuals or entities), it does not contain any limit on the *amount* of enrollee liability that can be imposed under a M+C private fee-for-service plan for services furnished by a non-contracting provider. While section 1854(e)(4) limits the actuarial value of cost-sharing overall, it does not limit the amount that can be charged for a particular service, except as specified elsewhere in this rule, for example limits for emergency services as established in section 422.112(b). Hence, except for limits specified elswhere in this rule, M+C organizations that offer M+C private fee-for-service plans will be able to establish cost-sharing for services of non-contracting providers without regard to a specific limit per service.

In § 422.216(c)(1) we specify that an M+C organization that offers an M+C private fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section. We also specify in § 422.216(b)(1)(iv) that if the M+C organization fails to enforce the limit as required by paragraph (c)(1) of this section, the organization is subject to intermediate sanctions under subpart O of this part. We intend to leave to the organization's discretion the means by which it will enforce the limits on charges to enrollees. However, through the ongoing monitoring of the M+C private fee-for-service plan, HCFA will review the means by which the plan is enforcing the limits on charges to enrollees by looking at the extent of complaints from enrollees and the action the M+C organization takes to resolve them, both systematically and individually.

In § 422.216(c)(2) we specify that an M+C organization that offers an M+C private fee for service plan must monitor the amount collected by non-contract providers to ensure that those amounts do not exceed the amounts

permitted to be collected under paragraph (b)(2) of this section. The M+C organization must develop and document violations specified in instructions and must forward documented cases to HCFA. HCFA may impose the sanctions provided in section 1848(g)(1)(B). These are the penalties that apply to nonparticipating physicians who fail to abide by the limiting charge under original Medicare.

In § 422.216(d) we specify that the M+C organization that offers an M+C private fee-for-service plan must provide to plan enrollees an appropriate explanation of benefits that includes a clear statement of the enrollee's liability, including any liability for balance billing consistent with this section. Section 1852(k)(2)(C)(i) requires that the plan must notify the enrollee of balance billing that can be collected by the provider. We believe that it would be misleading for this notice to be limited to the balance billing that can be collected by the provider since the provider may also be able to collect deductible, coinsurance and or a copayment from the enrollee (depending upon the plan's policy) and that therefore the plan should notify the enrollee of all cost-sharing and balance billing that can be collected by the provider so that there is no confusion.

We also specify that, in its terms and conditions of payment to hospitals, the M+C organization must require a hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to $500 or more, notice that balance billing is permitted for those services and a good faith estimate of the likely amount of balance billing, based on the enrollee's presenting condition. Section 1852(k)(2)(C)(ii) requires that such a notice be furnished by a hospital for inpatient services and permits the Secretary to require such a notice for other hospital services at a tolerance to be set by the Secretary. We believe that this requirement was included in the law because of the potential for the balance billing provisions that apply to contracting providers to create quite large liability for enrollees of these plans. For example, if an M+C private fee-for-service plan permits a hospital to balance bill up to the 115 percent of plan payment rate that the law would permit, and the plan payment is $10,000 for the hospital stay, the enrollee would be liable for $1500 in balance billing in addition to the deductible, coinsurance and copayment the plan permits the hospital to collect.

We specify that the advance notice requirements applies to all services furnished by a hospital because of the trend towards furnishing services on an outpatient basis that would previously have been furnished on an inpatient basis. These services can be very expensive and we believe that the enrollee has a need to know the cost-sharing for these services in advance of receiving the services as for inpatient hospital services.

We have set the tolerance at which the hospital must provide this advance notice at $500, which is the tolerance for nonparticipating physicians to provide advance notice of the nonparticipating physician's actual charge under section 1842(m)(1) for purposes of Part B of original Medicare.

In § 422.216(e) we specify that the M+C organization must comply with the coverage decisions, appeals, and grievances procedures of subpart M. This requires that the M+C organization, offering the M+C private fee-for-service plan, make coverage determinations on all services and that it must make a determination before the service is furnished if the enrollee or provider requests it. We believe that this requirement is necessary to enforce the provisions contained in section 1852(g)(1)(A), which apply to all M+C organizations. Specifically, section 1852(g)(1)(A) requires that ''A Medicare+Choice organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such services. Subject to paragraph (3), such procedures shall provide for such determinations to be made on a timely basis.'' Paragraph (3) is the expedited decision process.

We recognize that providing advance determinations of coverage has not been a common feature of commercial fee-for-service plans in the past. However, the law's use of the present tense with regard to the requirement for coverage determinations and its reference to the expedited appeals process (which is intended to obtain a quick appeal of a denial of a service not yet furnished) clearly anticipates that there will be the opportunity for an advance determination of coverage for all M+C plans. Moreover, the opportunity to acquire an advance determination of coverage is particularly important since there is no protection from retroactive denial for enrollees in an M+C private fee-for-service plan. This is a source of great risk for enrollees in M+C private fee-for service plans, who, unlike enrollees in coordinated care plans, may seek treatment from any licensed provider that agrees to accept the terms and conditions of the plan.

While the opportunity for advance determinations of coverage presents the opportunity to minimize the risk by giving the enrollee and provider the opportunity to determine whether the plan will pay for the service and the amount for which the enrollee will be liable, it does not provide protection to the enrollee that is comparable to the protection provided by original Medicare under the provisions of section 1879 (which apply to assigned claims) and under 1842(l) (which apply to unassigned physician claims). These provisions hold the beneficiary without fault when a services is denied as not medically necessary to treat illness or injury unless the beneficiary was advised by the provider in advance of the service that Medicare would not pay and the beneficiary accepted liability if Medicare did not cover the service. These provisions also permit a physician to take assignment on a claim for Medicare services to be found to be not at fault and to be paid by Medicare for the noncovered service if he can demonstrate that he did not know and could not reasonably have known that the service was not covered.

We considered and rejected imposing several requirements that would have provided Medicare beneficiaries with protection like that available under original Medicare. Specifically, we considered requiring that the M+C organization must require that contracting providers (including deemed contractors) submit claims for the services they furnish to enrollees. We also considered but rejected requiring the M+C organization to require that contracting providers (including deemed contractors) assume the responsibility for acquiring an advance determination of coverage from the plan or risk being unable to charge the enrollee if they did not notify the enrollee in advance of the service if the plan does not cover the care. This approach would have provided enrollees protection from the liability of full payment in the case of retroactive denials and would have given providers an opportunity to minimize their risk by acquiring advance approval of coverage.

However, we decided that it would be contrary to the spirit and intent of the M+C fee-for-service legislation to impose these requirements on providers and plans, since they would make the plan much more like a coordinated care plan than like a traditional fee-for-service plan. Moreover, such a construction would place the provider at financial risk, contrary to the

definition of an M+C private fee-for-service plan.

Our silence in regulations on the claims filing requirements of M+C private fee-for-service plans and the absence of any explicit mechanism for providing protection to enrollees from retroactive denials of coverage does not foreclose the possibility that an M+C private fee-for-service plan may choose to address these issues. For example, the M+C private fee-for-service plan may choose to include in its terms and conditions of payment a requirement that the provider must bill the plan for payment. Similarly, the M+C private fee-for-service plan may choose to provide some level of payment for services subject to retroactive denials as an additional benefit or as a supplemental benefit under the plan. This could be an attractive feature of the plan and a valuable benefit to enrollees.

Although we are silent on these issues, we remain concerned about the absence of protections for beneficiaries who enroll in private-fee-for-service plans. We are soliciting comments on these issues, and we are particularly interested in comments on whether to apply the protections discussed above as a requirement or how otherwise to protect the beneficiary from being financially at risk, while not creating undue burdens on providers and insurers.

In § 422.216(f) we specify that any provider that does not have a contract will be treated as having a contract in effect with the M+C organization offering the M+C private fee-for-service plan if the provider furnishing services (1) is aware that the beneficiary receiving the services is enrolled in the plan, and (2) before furnishing the services, has a reasonable opportunity to be informed about the terms and conditions of payment and coverage under the plan. Section 1852(j)(6) requires that we deem a noncontracting provider to be a contracting provider when these criteria are met. In § 422.216(f) we further specify three general criteria, each of which must be met for a provider to be deemed to have a contract with the plan and which are discussed further in § 422.216(g) and (h).

In § 422.216(f) we specify that for the deemed contract provision to apply the services must be covered under the plan and must be furnished to an enrollee of an M+C private fee-for-service plan, by a provider that does not have in effect a signed contract with the M+C organization. We also specify in § 422.216(f)(2) that the provider must have been informed of the individual's enrollment in the plan and must have been informed or given a reasonable opportunity to obtain information about the terms and conditions of payment under the plan in a manner reasonably designed to effect informed agreement. The information must include the information described in § 422.202(a)(1).

In § 422.216(g) and (h) we further clarify that the requirements of paragraph (f) of this section are met (and the noncontract provider is subject to the provisions for contracting entities) if the following conditions are met.

Enrollment information must be provided by one of the following methods or a similar method:

- Presentation of an enrollment card or other document attesting to enrollment.
- Notice of enrollment from HCFA, a Medicare intermediary or carrier, or the M+C plan itself.

We considered how best to ensure that the noncontracting provider would be advised that the enrollee is enrolled in the M+C private fee-for-service plan. However, since there is no direct contract between the provider and the M+C private fee-for-service plan, it becomes incumbent upon the enrollee to advise the provider of the enrollment. Even where the provider had previously been notified of the beneficiary's enrollment in the M+C private fee-for-service plan (e.g. at the time of a previous service), the provider cannot automatically assume that the beneficiary is enrolled in the plan and may not be able to learn the beneficiary's enrollment status prior to providing services. This occurs because, before 2002, beneficiaries can disenroll from M+C plans at any time, either voluntarily or involuntarily by moving out of the service area. After that date, the beneficiary can disenroll within the first 3 months of the year or at any time if they move out of the service area. Hence, there are very few times that a noncontracting provider can know with certainty that the beneficiary remains enrolled in the M+C private fee-for-service plan based on previous knowledge of enrollment. If the provider fails to acquire current enrollment information from the enrollee or the plan at the time of each service, we do not see how he or she can be held to have met the first test of ''deemed contract status'': knowing that the beneficiary is enrolled in the plan.

To be a deemed contractor, the provider or supplier who knows that the patient is enrolled in the plan must either have been given information on payment terms and conditions or must have had a reasonable opportunity to learn such terms and conditions of plan payment. Under that circumstance, treatment of the patient implies consent to the terms and conditions of plan payment.

To meet the requirement of having been given information on payment terms and conditions, we specify in paragraph (h)(1) that the information must have been communicated to one of the following:

- The provider of the services.
- The provider's employer or billing agent.
- A partnership of which the provider is a member.
- Any party to which the provider makes assignment or reassigns benefits.

We expanded the list of parties to whom the information must be provided beyond those of providers themselves in recognition that providers, and in particular, individual physicians and practitioners, seldom receive the insurance information that is sent to them and seldom complete and submit their own claims. By reassigning insurance benefits to other parties and by delegating the responsibility to complete and submit claims to other parties, they are, effectively, also delegating the authority to make decisions governing their payment for which they remain responsible.

We also specify in paragraph (h)(1) that the information must have been transmitted via mail, FAX, electronic mail or telephone. Announcements in newspapers, journals, or magazines or on radio or television are not considered communication of the terms and conditions of payment. We specify how the information must have been provided because we have been asked if general distribution of information to the public (e.g. annual newspaper notice) is an acceptable notice to bind the provider to being considered to be a deemed contractor. We do not believe that it is reasonable for a plan to do a general public notice since the provider may not see it and has no way of relating that information to itself. However, where the plan has transmitted the information directly to the provider by mail, FAX, electronic mail or telephone, the statute's test of having been furnished the information to the provider has clearly been met.

However, the law also provides that a provider that has a reasonable opportunity to acquire the terms and conditions of plan payment must be treated as if it were a contract provider. To implement this provision of the law, we further specify in paragraph (h)(2) that a provider that does not have a contract with the plan is deemed to have a contract with the plan if the plan has an acceptable procedure under which the provider could acquire the

terms and conditions of plan payment before providing services to the enrollee. Specifically, we say that this test is met where the M+C plan has in effect a procedure under which noncontract providers are advised how to request the payment information and the plan responds to the request before the provider furnishes the service. This procedure could be the inclusion of a toll free telephone number or E-mail address on the enrollment card for the provider's use in acquiring the terms and conditions of payment. Where the plan responds to the provider's request before the service is furnished, the provider would be treated as a contract provider if the provider subsequently furnishes the service to the enrollee, regardless of whether the provider agrees to accept the terms and conditions of the plan.

The effect of these statutory provisions is that there are very few circumstances in which a provider would not be treated as if it had a contract with the plan. These would include but not be limited to the following:

- Where the beneficiary did not notify the provider of enrollment in the plan.
- Where the provider requested but was not furnished terms and conditions of payment in advance of the provision of services to a known enrollee.
- Where the plan did not have a process that provided terms and conditions of payment.

We think that in most cases, plans will ensure that there is a procedure in place for providing this information before services are furnished. We think that the most likely circumstances in which a provider will be considered to be a noncontracting provider will be in cases of emergency where the provider has not previously been mailed the terms and conditions of payment under the plan or where the provider does not know that the beneficiary is enrolled in the plan.

In § 422.216(h)(2)(iii) we specify that the plan must include the following in the terms and conditions of plan payment that it must furnish to providers of services:

- Billing procedures.
- The amount the plan will pay towards the service.
- The amount the provider is permitted to collect from the enrollee.
- The information described in § 422.202(a)(1).

V. Regulatory Impact Statement

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

The Unfunded Mandates Reform Act (Public Law 104–4) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in an annual expenditure of $100,000,000 or more.

Summary of the Interim Final Rule

As discussed in detail above, this rule implements the M+C program as directed by the BBA of 1997. The primary objective of the M+C program is to increase the number and types of health plan choices available to Medicare beneficiaries.

Since the implementation of section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA 82) (Public law 97–248), the Medicare program has offered beneficiaries a prepaid capitated option through HMOs and CMPs paid on a full risk basis. Enrollment by Medicare beneficiaries in Medicare managed care risk plans has grown to over 4.5 million enrollees. The number of plans increased 31 percent in CY 1995, 36 percent in CY 1996, and 31 percent in CY 1997. With the implementation of the M+C program, we expect that the rate of growth of beneficiaries enrolling in capitated plans will continue.

The M+C program authorizes HCFA to contract with several new types of entities not previously available to Medicare beneficiaries such as provider sponsored organizations, preferred provider organizations, entities offering an ''MSA plan'' and a contribution into an M+C medical savings account (MSA), and M+C private fee-for-service plans. These new options will provide Medicare beneficiaries with a broad range of health insurance alternatives like those available in the private sector. Based on current growth rates and other information discussed later, we estimate that anywhere from 160 to 800 new entities may apply to contract with HCFA as M+C organizations.

By expanding choices and providing extensive educational materials through a coordinated open enrollment period, it is expected that beneficiaries will choose plans and health delivery systems that will maximize the benefits to these individuals.

The BBA also revamped the payment methodology for entities receiving capitated payments from Medicare. These payment changes were intended primarily to insure that the amounts paid to M+C organizations were fair and equitable to both the Medicare Trust Funds and to the participating organizations. Although Medicare's capitation rates had been set at 95 percent of expected costs based on actual fee-for-service costs, there is significant evidence that Medicare has paid more for enrollees in the managed care program than it would have paid in the fee-for-service program. This is due primarily to the favorable selection that these plans have experienced. The new payment rules slow the annual increase M+C organizations would have received under the old payment methodology. In addition, there has long been concern regarding the regional variation in payment rates, particularly between urban and rural counties. Because the capitated payment rates had been based upon the fee-for-service payments, the capitated rates not only included the variation in local prices, they also reflected different fee-for-service practice patterns in each region. To level out the variation in payment rates, the new methodology uses a blend of local and national rates and input price adjustments to insure the payments more closely reflect the different prices in the region while giving less weight to the different utilization rates. Finally, to insure that the new options would be

viable in all parts of the country a floor on capitated payments was introduced.

Summary of Discussion of Impact

We believe that the overall impact of this regulation should be beneficial to Medicare beneficiaries by providing them with more options to receive health care. However, although many of the provisions in this regulation are intended to assist beneficiaries by providing them with comparative information, we are concerned that the many new choices and types of plans may prove confusing even for the most knowledgeable consumers. Reductions in capitated payment amounts in what are now relatively higher payment areas may result in reduced benefits for beneficiaries. Providers (especially rural providers) should benefit from this regulation because they can contract directly with HCFA under the PSO provisions. New contracting entities will benefit as the Medicare statute has not previously permitted entities that were not state licensed HMOs or CMPs to participate in the Medicare managed care program. Providers could be negatively impacted if they contract with M+C organizations by the degree that any reduction in the rate of growth in payments to M+C organizations will be passed on to them. We also recognize that existing contractors and States may be adversely affected but cannot quantify to what degree. This impact analysis will focus on the provisions of the BBA and this regulation that significantly alter the risk program we have been administering since 1985. The major differences between the section 1876 risk program and the M+C program are:

The coordinated open enrollment and public education campaign:

New payment methodology for contracting plans

Introduction of New Contracting Entities

Provider Sponsored Organizations

Medicare Savings Account Plans

Private Fee-for-Service Plans

New Quality Standards

Our analysis will assess the impact these changes will have on Medicare beneficiaries, the Medicare Trust Funds, providers, managed care entities, and States. Whenever possible, we will use appropriate methods for assessing the impact quantitatively. However, because of the large number of unknowns—such as the prospective number of contracting organizations—this analysis relies upon many simplifying assumptions.

B. Coordinated Open Enrollment and Public Education Campaign

Section 1851 directs HCFA to hold annual coordinated open enrollment periods beginning in November 1999 (all plans will also be open to enrollment in November 1998) to allow eligible beneficiaries the opportunity to enroll in M+C organizations. It also directs HCFA to broadly disseminate information to current and prospective Medicare beneficiaries on the coverage options available in order to promote an active, informed selection among such options. At least 15 days before each annual, coordinated election period, HCFA will send to each eligible individual a notice containing information in order to assist the individual in making an election. This information describes M+C options as well as original Medicare. In addition, M+C organizations are directed to provide plan-specific information.

The public education campaign will include information on covered benefits, cost sharing and balance billing liability under the original Medicare program; election procedures; grievance and appeals rights under the original Medicare fee-for-service program and the new M+C program; information on Medigap and Medicare SELECT; and the beneficiary's right to be protected against discrimination based on health status.

The costs of the coordinated open enrollment and public education campaign will be borne primarily by the participating M+C plans. Section 4001 of the BBA added a new section 1857(e)(2) to the Social Security Act that establishes a fee requirement under which M+C organizations and section 1876 contractors must contribute their pro rata share, as determined by the HCFA, of costs related to enrollment, dissemination of information, and the counseling and assistance programs.

The annual fee will be assessed by HCFA on all participating organizations. The amount of the user fee will vary year to year as determined through the appropriations process. The BBA authorized ceiling amounts of $200 million in FY 98, $150 million in FY 99, and $100 million annually in FY 2000 and beyond. However, in FY 1998 HCFA was authorized to collect only $95 million through the appropriations process.

On December 2, 1997 HCFA gave notice of our methodology of assessing current contractors for their pro rata share of the expenses associated with the CY 1998 information campaign. To determine each organization's share, we divided the total amount appropriated for the information campaign by the total projected revenues for the first 9 months of CY 98. The resulting percentage was deducted from the payments to contracting organizations.

We explored several alternatives to this methodology. One option was to assess each organization on a per capita basis (by number of Medicare enrollees). Another option was to assess each organization on the percentage of revenue they received from capitated Medicare payments, but have a cap on the highest amount any organization would pay.

We rejected both of these methodologies as not consistent with the goals of the BBA. One of the primary effects of the reformed payment methodology of the BBA was to even out variation between high and low payment areas. By charging a per capita amount, those organizations that are located in areas that have a high payment rate would pay a reduced percentage of their revenue. Or put another way, we deemed that if an organization received a higher payment per person, it should pay a correspondingly higher user fee for its share of the education campaign. We also decided not to put a cap on the assessment any organization would receive based on the premise that only large organizations would receive the benefit of a cap and smaller organizations would have to pay more to make up the difference. This did not seem fair or consistent with our intention of encouraging the creation of new contracting entities and spurring competition in areas with lower payment rates.

As stated in the interim final rule (M+C Program: Collection of User Fees from M+C Plan and Risk-Sharing Contractors (42 CFR 417.470–417.472)), we will establish a fee percentage rate and collect the fees over nine consecutive months beginning with January until the assessment limit has been reached. The following table illustrates the method by which we will calculate the fee percentage rate, provides the rate for FY 1998, and sets forth projections for FY 1999–2002.

TABLE 1.—COLLECTION OF CONTRIBUTIONS FROM ORGANIZATIONS FOR COSTS RELATING TO INFORMATION DISSEMINATION

	Projected fiscal year total medicare payment to organizations (in millions of dollars) [1]	Projected medicare payment to organizations per month (in millions of dollars) [2]	Projected medicare payment to organizations over 9 months (in millions of dollars) [3]	Authorized assessment amount (in millions of dollars) [4]	Fee amount secretary is directed to collect (in millions of dollars) [5]	percentage of projected 9-month payment
FY 1998	30,000	2,465	22,181	200	95	.428
FY 1999	38,000	3,167	28,500	150	150	.526
FY 2000	47,000	3,917	35,250	100	100	.284
FY 2001	63,000	5,250	47,250	100	100	.212
FY 2002	64,000	5,333	48,000	100	100	.208

[1] Source: Congressional Budget Office, The Economic and Budget Outlook: Fiscal Year 1999–2008. January 1998.
[2] Projected total fiscal year payment divided by 12 (months).
[3] Projected monthly payment amount multiplied by 9 (months).
[4] New Section 1857(e)(2)(D) of the Social Security Act, as added by the BBA (Public Law 105–33).
[5] For purposes of these projections, we have assumed that Congress will include the full amount authorized under the BBA.

As noted in the interim final rule published on December 2, 1997, we believe that assessing the fees to reflect an organization's pro rata share of the expenses associated with the information campaign will require the deduction of only a very small percentage of any organization's total annual Medicare payments. For example, in FY 1998 the percentage fee assessment is 0.428 percent—less than one-half of one percent. In subsequent fiscal years the fees as a percentage of Medicare payments will likely represent an even smaller percentage of the Medicare payments as the number of eligible organizations increase and the existing organizations experience enrollment growth.

Information Campaign

In general, we believe that this investment in new forms of information dissemination should be beneficial to Medicare beneficiaries, contracting organizations, and the Medicare program. By providing extensive educational materials, it is expected that beneficiaries will choose organizations and health delivery systems that will maximize the benefits for them. Finally, while organizations face an assessment fee to support information campaign activities, it comprises a very small proportion of their revenue from the Medicare program and could serve to enhance their marketing efforts and to save marketing expenditures.

HCFA's information dissemination activities provided for under this regulation encompass a variety of interventions, including mailings of standardized, comparative information about coverage options, an Internet web site with such information, and a toll-free telephone line for beneficiary inquiries. In addition, the regulation provides for information dissemination activities to be undertaken by M+C organizations, including mailings to Medicare enrollees of plan-specific information and the provision of additional information upon request by Medicare eligible individuals.

In order for market competition to work effectively, consumers must have information about their choices in order to make good decisions. The information dissemination efforts provided for under this regulation will give Medicare beneficiaries information about the Medicare market, enabling them to compare fee-for-service coverage to managed care coverage, as well as coverage under different M+C organizations.

The Medicare program and managed care arrangements are inherently complex subjects, and it is challenging to communicate information that is meaningful and accurate. Many studies have shown that Medicare beneficiaries' level of understanding of how the Medicare program works today is very low (GAO, 1996) and this lack of understanding could be compounded by the introduction of a new array of choices if beneficiaries lack sufficient information or lack the skills or understanding necessary to use available information.

For example, studies have found that many individuals who disenrolled from Medicare risk HMOs misunderstood the nature of the plan, such as the lock-in feature. (OIG, 1997; GAO, 1996; IOM, 1996). As Medicare beneficiaries become better informed about the Medicare program generally and their options under M+C specifically, they will be able to make more informed decisions about meeting their health care needs, leading to fewer disenrollments based on misunderstandings. Disenrollment can be costly for plans. In 1996, a GHAA study estimated that disenrollment costs plans close to $1,300 per Medicare disenrollee. (GHAA, 1996)

While enhancing beneficiary choice is positive and providing beneficiaries with information on their choices is necessary, we are concerned that Medicare beneficiaries, especially in areas where several M+C organizations are operating, may experience information overload. Beneficiaries may have great difficulty in understanding the different types of plans available to them in their area or understanding the different benefit packages plans may offer. Beneficiaries will be required to assess their health needs in relation to the benefits being offered and they may well have to choose among a wide array of different benefit packages. These will be difficult choices and some beneficiaries may not choose the option best suited to their individual needs.

We believe important secondary effects may ensue as well. To date, plans have competed primarily on the basis of price and benefits. Broad dissemination of plan-specific information, including quality measures, should encourage competition among organizations based on quality factors, in addition to price and benefits. As Medicare beneficiaries become more familiar with health plans, their expectations of plan performance and quality services will increase. Enhanced beneficiary awareness will provide an incentive to plans to improve in areas that beneficiaries demonstrate are important to their decision making, such as the availability of certain providers and positive customer service experiences.

Moreover, beneficiaries will be better health care consumers in general if they understand their rights under managed

care and how to make a plan work for them. As Medicare enrollees receive more information and become more active decision makers on plan options, we believe they will also become more informed and active decision makers with respect to meeting their personal medical needs. More informed and active decision making on the part of enrollees will, in turn, facilitate plans' efforts to manage the delivery of appropriate, high quality health care services.

In addition, it should be noted that the information campaign is designed to reach all Medicare beneficiaries, and it is likely that, to the extent that this encourages growth in the M+C program, organizations will be well positioned to take advantage of the expanding market. Since the number of organizations and total revenues over which the BBA fee collections will be spread is likely to continue to rise with increased participation in the M+C program in future years, we believe the regulatory impact of the selected option for imposition of fees on M+C organizations will not be significant. Moreover, M+C organizations will benefit from the increased visibility they will receive through the focused information campaign each open enrollment season.

Aside from the benefits of the public education campaign there are benefits derived from the coordinated open enrollment for contracting organizations, beneficiaries, and to a lesser degree the Medicare Trust Funds, as discussed below.

Coordinated Open Enrollment and Beneficiary Lock-In

We anticipate that the transition into a coordinated open enrollment period and the beneficiary lock-in will be beneficial to M+C organizations in their efforts to attract and retain Medicare enrollees. It also will allow them to maximize their visibility as beneficiaries focus on information about plans during a single, coordinated period. An annual open enrollment period may present a challenge for start-up organizations that did not have the benefit of adding enrollment during continuous open enrollment periods available before 2002. However, the M+C beneficiary lock-in will provide a more stable enrollment base for all participating organizations.

Current contractors have conveyed that continuous open enrollment, which was prevalent prior to passage of the BBA, provided an incentive for beneficiaries that exhaust extra benefits offered by one HMO/CMP to switch to another HMO/CMP or back to traditional fee-for-service Medicare. This behavior provides a disincentive for M+C organizations to offer extra benefits, and we anticipate that M+C organizations will be more likely to offer extra benefits if concerns about enrollees disenrolling upon exhausting a benefit are diminished.

Moreover, as the lock-in is phased in, organizations offering M+C plans will operate within a framework that supports their efforts to manage the delivery of health care services. For example, if beneficiaries are not moving in and out of a plan, the M+C organization offering the plan will be better able to track a beneficiary's utilization of services over time. The lock-in will encourage plans to invest more in preventive health services or screening of new enrollees, because it increases the likelihood that the plan will retain its members long enough to benefit from eventual savings due to reduced morbidity. (PPRC, 1996)

We also note that M+C organizations will have to address the potential staffing and administrative requirements associated with a lock-in and a compressed enrollment period, such as how to staff appropriately to handle inquiries during the open enrollment period, how to process new enrollees when enrollment begins, and how to conduct initial physical histories and review medications for new enrollees. Therefore, there will be added burdens on the M+C organizations as they experience administrative and clinical burdens in implementing the lock-in. M+C organizations may have to hire temporary staff and this would be a cost to them (PPRC, 1996)

Although beneficiaries will have less flexibility with a lock-in period, they will also benefit from a coordinated open enrollment period because it provides a framework conducive to informed decision making. Similar to the experience of many individuals in the private sector, beneficiaries will receive extensive information each year, allowing them to compare all options simultaneously. By receiving standardized, comparative information during an annual, coordinated period, beneficiaries will find it easier to make appropriate choices among competing plans and between these plans and traditional Medicare fee-for-service. An annual coordinated open enrollment period will maximize the opportunity for all beneficiaries to make decisions that best meet their own needs.

Some beneficiaries may be more reluctant to enroll in an M+C organization if they must remain enrolled for extended length of time. The Office of Inspector General surveyed a two-stage random sample of 4,065 enrollees and disenrollees from 40 Medicare risk HMOs to compare their responses and to gain greater insight into HMO issues. The majority of beneficiaries surveyed stated that their most important reason for joining an HMO was their desire for more affordable health care. Only 17 percent of beneficiaries said they would be more hesitant to join an HMO if they did not have the option to disenroll at will. (OIG 1998) (see Table 2).

TABLE 2.—EFFECT OF MANDATORY ONE-YEAR ENROLLMENT—1996

[In percent]

	All	Enrollees	Disenrollees
If beneficiary had to stay in HMO for one year, the effect on the enrollment decision would be:			
—more likely to join	34	34	22
—less likely to join	17	16	33
—no effect on decision	49	49	45

Source: U.S. Department of Health and Human Services, Office of the Inspector General, Beneficiary Perspectives of Risk HMOs 1996, OEI–06–95–00430 (March 1998).

Beneficiaries retain the protection of the right to disenroll where the M+C organization's misrepresentation or the beneficiary's misunderstanding results in an enrollment that should not have occurred. In addition, the year-long opportunity for newly eligible aged individuals to disenroll and return to original Medicare is a particularly valuable protection for many beneficiaries who may be just beginning to understand the implications of new

options. (Newly eligible disabled beneficiaries are not afforded this option.) Beneficiary protections are enhanced by guaranteed issue of Medigap policies for first-time M+C enrollees who gave up supplemental coverage upon enrolling in an M+C organization and disenroll within 12 months, and for newly eligible aged beneficiaries who enroll in an M+C organization at age 65 and disenroll within twelve months of becoming eligible for Medicare.

Finally, we believe the lock-in will benefit the Medicare Trust Funds. The General Accounting Office found that the flexibility for beneficiaries to disenroll at will can cause problems for the Medicare program. (GAO, 1997) For example, beneficiaries could decide to use an M+C plan or other private plans while in relatively good health but disenroll to fee-for-service when their health care needs increased. The result could be a disproportionate number of less healthy beneficiaries in the fee-for-service sector, excess payments to HMOs, and unnecessary Medicare spending. We believe that the nine-month lock-in period will help reduce risk selection and, consequently, reduce the current problem of paying monthly premiums for beneficiaries while they are healthy but paying traditional claims when they become ill and disenroll from a managed care plan.

C. New Payment Methodology for M+C Plans

Section 1853 directs HCFA to modify the payment methodology for entities receiving capitated payments from Medicare. These payment changes are intended to: promote savings, reduce geographic variation in the rates, and stimulate the growth of new entities to serve Medicare beneficiaries in historically underserved areas. As described above, beginning in 1998, monthly county rates are the greatest of: (1) a minimum payment amount (of $367 in 1998); (2) a minimum percentage increase of 2 percent over the preceding year's payment for the area; and (3) a blend of the area-specific rate and an input-price adjusted national rate, further adjusted by a budget neutrality adjustment. The area-specific portion of the blended rates and the minimum payment amount are updated each year by the national average per capita Medicare growth rate (with specified reductions from 1998–2002).

Payment changes to M+C organizations figure prominently in reducing overall Medicare spending and postponing the depletion of the Medicare Trust Fund from 2001 to 2010. The CBO estimates that the BBA reduces Medicare spending by $116.4 billion dollars between 1998 and 2002. An estimated $22.5 billion, or almost 20 percent of total Medicare savings under the BBA, is attributable to payments to M+C organizations. Much of the savings is attributable to lower payment rates in the original Medicare program. Additionally, removal of GME and IME from the capitated payments to M+C organizations represents a redirection of $4 billion, which would be paid directly to providers. All told, the BBA payment changes are estimated to reduce annual spending increases for both the M+C program and original Medicare from 8.5 percent to about 5 percent a year between 1997 and 2002.

The new payment methodology will lessen the significant geographic variation in payments by reducing the influence of factors that cannot be explained by geographic differences in medical input prices. Under the pre-BBA methodology, capitation amounts were based on actual per capita costs for original Medicare in each enrolled's county of residence. Under the BBA formula, adjustments for input prices is specifically included in the computation of blended rates, but the influence of practice pattern differences is gradually minimized through the payment blending. Over the period 1998–2002, each county's blended payment amount is increasingly based upon a standardized rate that reflects practice patterns across the country. In this way, the new methodology attempts to achieve a more equitable distribution of payments, and will hopefully encourage plans to focus on implementation of quality-based, cost-effective treatment methods.

One of the chief considerations in restructuring the payment methodology was evidence that Medicare managed care organizations have attracted healthier and therefore less expensive enrollees than fee-for-service organizations. In its 1996 Annual Report to Congress the PPRC reported on a study of enrollees in Medicare risk plans between 1989 and 1994. This study showed that those enrolled in managed care plans cost the Medicare program only 63 percent as much as the average Medicare beneficiary during the six months preceding enrollment when both groups were enrolled in traditional Medicare. In contrast, persons who disenrolled and returned to traditional fee-for-service Medicare cost the program 160 percent as much as the average beneficiary in the six months following disenrollment. In its December, 1997 study, the Congressional Budget Office estimated that Medicare paid 6–8 percent more for enrollees in risk-based HMOs than it would have paid for those enrollees under fee-for-service Medicare. Although prior law did set Medicare capitation rates 5 percent below fee-for-service payments under original Medicare, this reduction was not enough to compensate for favorable risk selection. The new methodology mandated by the BBA requires risk adjustment beginning in the year 2000.

Medicare managed care enrollment has grown steadily in recent years. However, most of the growth has been concentrated in urban areas. Between December of 1990 and December of 1997, enrollment in risk contracts grew from 3.3 percent of Medicare beneficiaries to 14.0 percent. Twenty-four percent of beneficiaries residing in large urban areas with a population of 1 million or more were enrolled in a Medicare risk plan in June of 1997. Twelve percent of beneficiaries residing in areas adjacent to large urban areas and smaller metropolitan areas, and less than 3 percent of Medicare beneficiaries residing in rural areas, were enrolled in a Medicare risk plan. Approximately thirty-three percent of Medicare beneficiaries reside in an area that is not served by any Medicare managed care organization.

We assessed the impact of the payment methodology by first considering the overall impact and then considering the impact of changes in payment on specific entities. The potential overall impacts of changes in payment are: reductions in spending; redistribution of payments; increases in enrollment in M+C plans; changes in the distribution of enrollment in M+C plans; and the creation of a more competitive market offering a wider range of choices for Medicare beneficiaries.

We have identified the types of entities and individuals that will be directly affected by changes in payment. They include: beneficiaries, M+C organizations offering coordinated care plans (including current Medicare managed care contractors), and M+C organizations offering private fee-for-service plans or MSA plans, States, providers, and the Medicare Trust Funds.

One clear impact of the revised payment methodology is decreased spending relative to estimates of spending under prior law. In its BBA analysis, CBO estimated that changes in payments to managed care plans save $22.5 billion between 1998–2002. As stated earlier, these savings contribute significantly toward efforts to extend the long-term solvency of the Medicare Part

A Trust Fund. Table 3 provides more recent alternative projections of $30 billion in savings between 1998–2003. (HCFA Office of the Actuary, 3/98.)

TABLE 3.—PROJECTED IMPACT DUE TO CHANGES IN PAYMENT METHODOLOGY

Fiscal year	Savings (in billions of dollars)
1998	0.3
1999	0.7
2000	4.4
2001	6.6
2002	8.1
2003	9.2

*Includes risk adjustment.
Source: HCFA Office of the Actuary, 3/98.

As noted above, projected savings due to the change in the M+C payment methodology are also tied in part to the overall savings in Medicare created by BBA changes in payments to Medicare fee-for-service providers. Specifically, since the National Per Capita M+C growth factor (NGP) is defined as the ''projected per capita rate of growth in Medicare expenditures'' reduced by the BBA's specified percentage reduction, the NGP will include the impact of reductions and/or slower increases to provider payments in the original Medicare program.

Another factor that affects the amount of savings is the minimum payment amount and the minimum percentage increase. Because the payment methodology does not allow for reduction of the floor and minimum payment increases, budget neutrality, which is achieved by reducing or increasing the blended rates, may not be achieved in all years where the computation requires a reduction in the blended rates. This situation occurred in the calculation of the 1998 and 1999 rates, when no county received the blended rate because the budget neutrality adjustment brought all rates to an amount below the amount of the minimum 2 percent increase. See discussion in Section II.F. above.

It is clear that one aspect of the new payment methodology, the floor, actually increases spending compared to prior law. CBO estimates that increasing payments to the floor counties will cost $2.2 billion more than expected under previous law over the 5-year period of 1998–2002. However, increasing payment to floor counties meets important policy objectives in that by reducing payment disparities it is hoped that more choices will become available in under-penetrated areas.

The payment methodology has removed some of the variation in payment rates by increasing payment rates in lower payment counties through use of a minimum payment amount. In the future, blending will further reduce variation by reducing the influence of local fee-for-service costs in the blended rates. Table 4 shows the impact of the payment methodology by location. The floor rate increased payments significantly in rural areas and in some urban counties as well.

TABLE 4.—AVERAGE AND RANGE OF MEDICARE COUNTY PAYMENT RATES, BY LOCATION, 1997–1998

	1997 Average	1998 Average	1997 Range (Low:High)	1998 Range (Low:High)
All Counties	470	484	221:767	367:783
Central Urban	546	557	349:767	367:783
Other Urban	440	452	256:728	367:742
Urban Fringe	394	413	231:693	367:707
Other Rural	371	397	221:647	367:660

Source: MEDPAC, March 1998 Report to Congress: Medicare Payment Policy.

A further change in the methodology is the graduate medical education (GME) carve-out. While the removal of GME does not generate savings for the Medicare trust fund or Medicare GME, it does reduce capitation rates in counties that historically received GME payments (except in counties where the minimum payment amounts apply). In general, GME carve-outs disproportionately affect urban managed care organizations because urban counties house more teaching hospitals. Table 5 shows the 1995 GME percentages in urban and rural counties.

TABLE 5.—ESTIMATED GRADUATE MEDICAL EDUCATION PAYMENT REDUCTIONS AS A PROPORTION OF MEDICARE RISK PAYMENT RATES BY URBAN AND RURAL LOCATION (PERCENTAGE), 1995

Location	GME percentage
All Counties	3.4
Urban Counties	3.8
Central Urban	5.3
Other Urban	3.1
Rural Counties	2.1
Urban Fringe	2.2
Other Rural	1.9

Source: PPRC, 1997 Annual Report to Congress, Chapter 3, p. 62.

We anticipate that these changes to the variations payment will affect the enrollment distribution of M+C enrollees.

The methodology has already increased capitation levels in rural areas now receiving the payment floor, in some counties significantly. HCFA's Office of the Actuary currently predicts that the blended rates will begin in CY 2000, which should increase rates in some rural areas that received the 2 percent increase in 1998 and 1999. In fact, to the extent that blended rates are eventually applied under the budget neutrality rules, the blended rate will gradually elevate payments to counties that have an area-specific payment that is below the national average as adjusted for input prices.

The improved incentives in rural counties should prompt M+C organizations to contract in these areas. Greater participation of managed care plans in rural counties should spur increases in M+C enrollment in the long run. CBO expects an incremental gain of 3 percent market share for coordinated care plans by 2002. This growth occurs, for the most part, in non-urban areas. It

is expected that higher payments in rural areas will encourage M+C organizations to offer plans in these areas. In particular, PSOs were included as an M+C option in part because of the belief that rural providers might organize M+C organizations in their areas which, because of their smaller population bases, generally have not been as attractive to managed care plans for commercial or Medicare business.

Table 6 provides a profile of the distribution of risk contractors and enrollment prior to passage of the BBA.

TABLE 6.—DISTRIBUTION OF MEDICARE RISK ENROLLMENT, AND RISK CONTRACTORS

Location	Percent of beneficiaries in risk plans (6/97)	Percent of counties offering 0 risk plans (6/97)	Percent of counties offering 1 risk plan (6/97)	Percent of counties offering 2–4 risk plans (6/97)	Percent of counties offering more than 5 risk plans (6/97)
Urban (MSA of 1 million or more)	24	0	2	19	79
Other Urban (surrounding counties or smaller MSA)	11.8	27	12	34	27
Fringe Urban (rural areas bordering MSA)	2.6	71	18	11	1
Other rural areas	1.1	91	6	3	0

Source: MEDPAC 1997 Chartbook.

It is expected that as more M+C organizations enter the Medicare market, competitive pressures will increase. As the payment changes are implemented and geographic variation in payment levels is reduced, the profitability of M+C organizations will be driven less by where they deliver services, and more by how well they deliver services. An organization's success will depend on the quality of services offered, the extent and clarity of an organization's communications with beneficiaries, the ability of a plan to effectively manage the provision of care to Medicare beneficiaries, and the satisfaction levels of Medicare enrollees in a plan, as well as the benefits offered and the premiums charged. These competitive forces should provide increased access to high quality services under capitated plans for Medicare beneficiaries.

For beneficiaries in rural areas we believe the overall impact of these changes should make participation in the M+C program a more viable option. Conversely, as payment rates become less robust in urban areas and margins decrease, some coordinated care plans may choose to reduce benefits, or increase premiums. Reductions in benefits or increases in premiums would have a negative impact on beneficiaries.

We should also note here that oftentimes we look at payment as a driving force in the Medicare program as a whole. While the increased payment to rural counties should on its face provide an incentive for organizations to offer their services and products in rural areas, that may not always be the case. That is, some may assume that when Medicare pays coordinated care plans considerably more than the average per capita fee-for-service cost in a geographic area, as it does in many of the payment floor counties, this would cause organizations to rush to enter into contracts in these areas. However, plans may decide that the smaller pool of potential enrollees (and hence the smaller pool over which to spread risk) do not justify either their added financial risk or the proportionally larger start up and marketing costs associated with launching a plan in a rural area.

We believe and Congress intended that these increases for rural counties would stimulate the growth of capitated plans in these areas. However, there still is a large degree of uncertainty over the actual effects of the BBA changes for rural areas. In the end only M+C organizations can really determine if the payment levels justify their costs.

D. Introduction of New Contracting Entities

In general, we believe that new entities will be formed to serve the Medicare market. As discussed above, the new payment methodology and the availability of PSO and MSA plans should stimulate the private sector's development of entities to compete for Medicare beneficiaries. While estimates of the development of new entities are somewhat speculative, the following are our best estimates based on currently available information, enrollment projections, informal surveys and discussions with industry representatives.

Provider Sponsored Organizations: The Congressional Budget Office projects that PSO enrollment will reach a 3 percent share of Medicare beneficiaries, or about 1 million beneficiaries, by 2002 and that a significant portion of the PSO enrollment will be in rural areas (CBO, 1997).

Currently, there are approximately 5.5 million beneficiaries enrolled in 307 Medicare risk products, which is an average of approximately 8,000 enrollees per Medicare risk plan. We believe that CBO's projections, presented in the following table, represent a good estimate of the approximate number of new PSO plans that will be established. Some industry analysts have projected a higher level of certified PSOs than projected by CBO. While we believe it is highly unlikely that as many as 25 PSOs will be certified by the end of 1998, we believe that CBO's projections for 1999 and thereafter are reasonable.

Enrollment estimate	Year	New PSOs
100,000	1998	25
400,000	1999	50
600,000	2000	75
800,000	2001	100
1,000,000	2002	125

Source of enrollment estimate: CBO, 1997.

As a secondary impact, the M+C program could result in expanded availability of PSOs, particularly in rural areas. That is, PSOs that are successful in their Medicare contracts may decide to expand into the commercial market. In turn, if commercial payers learn of their success in serving the Medicare population, they may have more confidence in the ability of PSOs to assume and manage risk and may, therefore, be more interested in contracting with them.

Private Fee-For-Service Plans: The Congressional Budget Office projected that no Medicare beneficiaries will enroll in private fee-for-service plans, and no reliable estimates for the number of likely private fee-for-service market entrants are available. However, we have received some expressions of

interest from insurance carriers and others regarding how these plans will work and whether there is an opportunity to serve Medicare beneficiaries. If offered, we would expect them to be most attractive to wealthier beneficiaries because of their anticipated higher premiums and other out-of-pocket costs. While private fee-for-service plan providers are allowed to engage in limited balance billing, there is no statutory limit on premiums that a plan may charge beneficiaries.

Medical Savings Account Plans: The Congressional Budget Office estimated that 390,000 Medicare beneficiaries will enroll in M+C MSA plans by 2000. This is the statutory limit for the total number of beneficiaries that can enroll in the MSA demonstration. While there are no reliable estimates on the number of organizations that will offer M+C MSAs, we expect that many organizations offering MSA plans in the commercial marketplace will offer MSA plans in the Medicare market as well.

According to a recent General Accounting Office study, 57 carriers, including three HMOs, offered MSA plans in the commercial market as of the summer of 1997. Blue Cross & Blue Shield plans represented almost one-third of the plans offered in the market. At that time, an additional fifteen carriers and eight HMOs indicated an interest in offering MSA plans. However, commercial enrollment in MSA plans has been considerably lower than had been anticipated. While the demonstration project under the Health Insurance Portability and Accountability Act allowed for 750,000 MSAs to be sold, as of June 30, 1997, only 17,145 individuals had enrolled in these new products, according to the Internal Revenue Service.

The GAO found that the complexities surrounding the tax implications of an MSA product, increased time necessary to explain the product to customers, and lower commissions to brokers/agents for selling a high deductible product have contributed to the low number of plans sold. However, some of these complexities may be mitigated under the BBA, as beneficiaries are barred from contributing their own money to the medical savings account, and they will receive extensive information about MSA plans as part of the annual information campaign on their M+C options.

Impact of New Contracting Entities

Beneficiaries may benefit from competitive pressures on M+C organizations to compete on such factors as reduced premiums, extra benefits, and quality. However, the difference between out-of-pocket costs under managed care plans and the traditional fee-for-service program may decrease as M+C payments moderate. Under the Medicare risk program, beneficiaries enrolled in risk HMOs generally have had lower out-of-pocket costs than beneficiaries in the traditional Medicare fee-for-service sector. For example, a recent study by the American Association of Retired Persons projected that beneficiaries enrolled in a Medicare managed care plan will spend an average of 16 percent of their annual income, or $1,775, on out-of-pocket health care costs, in 1997. This is compared to the estimated out-of-pocket expenses for Medicare fee-for-service beneficiaries, which were projected on average to be 21 percent of their annual income, or $2,454, on out-of-pocket costs. (AARP, 1997).

We also anticipate that many providers will have new opportunities to serve Medicare beneficiaries, such as through provider sponsored organizations or through strategic partnerships with other coordinated care plans seeking to enter new markets. As M+C enrollment grows, providers will find it increasingly important to their business to participate in an M+C network as many of their patients will be locked into these networks. In turn, we believe M+C organizations will seek to contract with providers that are capable of serving both their commercial and Medicare populations.

Finally, the M+C program will most affect those states in which the greatest market opportunities for newly created M+C organizations exist. Oversight and licensing responsibilities will likely increase for such states as newly created M+C organizations, such as PSOs, seek to serve the Medicare market. The BBA increases the workload for States only to the extent that new organizations will begin operating in the State. It is likely that States will also have to monitor the compliance of PSOs that have a waiver of State licensure in the case of quality and consumer protection standards. This constitutes an additional workload of partial monitoring of plans that are not subject to State solvency requirements.

Many states will be confronted with issues on licensing of PSOs, whether by bringing such entities under existing HMO laws and regulations or establishing separate PSO licensing provisions. In a recent report, the National Association of Insurance Commissioners reported that ten states have already enacted state-level PSO regulation (NAIC, 1997), and the National Council for State Legislatures reports that thirteen states currently are considering PSO legislation.

States will also have to integrate PSOs into their state guaranty fund or other mechanism for protecting beneficiaries against insolvent plans. While this will not be a new function, it is expected to increase the amount of regulatory oversight necessary due to new market entrants and could place burdens on a state's ability to protect consumers if PSOs become insolvent.

Finally, the preemption of state mandated benefit and provider participation laws will lead to mandated benefits being applied to a smaller number of State residents. However, states may still enforce any laws relating to cost-sharing for a benefit included in an M+C contract as well as any laws restricting balance billing practices by providers. Moreover, we believe that few states will be impacted by the BBA's prohibition on state imposition of premium taxes on payments to Medicare risk contracts/M+C organizations. While almost all states impose premium taxes on insurers generally (and nineteen states have specific premium tax schedules for HMOs), it is our understanding that most states have not subjected Medicare revenue to a premium tax and that many states specifically exempt Medicare payments to HMOs from any premium tax.

E. New Quality Standards

Each M+C organization must have arrangements for an ongoing quality assessment and performance improvement program for health care services it provides to Medicare beneficiaries enrolled in the M+C plans. The quality assurance program for an M+C organization must, among other things: (1) stress health outcomes and provide for the collection, analysis, and reporting of data to permit measurement of outcomes and other indices of the quality of M+C organizations and organizations; (2) include measures of consumer satisfaction; (3) provide the Secretary with such access to information collected as appropriate to monitor and ensure the quality of care; (3) provide review by physicians and other health care professionals of the process followed in the provision of health care services; (4) provide for the establishment of written protocols for utilization review, based on current standards of medical practice; (5) have mechanisms to detect both underutilization and overutilization of services; (6) take action to improve quality and assess the effectiveness of that action through systematic follow-up; and (7) make available information

on quality and outcomes measures to facilitate beneficiary comparison and choice of health coverage options.

An M+C organization is deemed to have met the quality assessment and performance improvement requirements if the organization is accredited (and periodically reaccredited) at a level acceptable to the Secretary by a national, private accrediting organization approved by the Secretary. Deemed M+C organizations must meet certain requirements, including submitting to surveys to validate its accreditation organization's process and authorizing its accreditation organization to release to HCFA a copy of its most current accreditation survey and any information related to the survey as required by HCFA.

Accrediting organizations will have to meet certain requirements in order to receive approval as well as ongoing requirements to maintain its approved status.

The quality assurance and performance improvement requirements under this regulation provide that each M+C organization achieve minimum performance levels on standardized quality measures. They also require that organizations conduct performance improvement projects that achieve, through ongoing measurement and intervention, demonstrable and sustained improvement in significant aspects of clinical care and non-clinical services that can be expected to affect health outcomes and member satisfaction. This approach to ensuring quality reflects the expansion in recent years of the problem-focused approach that was prevalent in the past to include a focus on systematic quality improvement as well.

We believe that the quality assessment and performance improvement requirements under this regulation will not impose significantly new burdens on most M+C organizations.

First, as discussed in detail in section III D of this preamble, requirements under this regulation build on a variety of HCFA and State Medicaid agency efforts to promote the assessment and improvement of quality in plans contracting with Medicare and Medicaid, including:

- The Quality Improvement System for Managed Care (QISMC), an initiative with state and federal officials, beneficiary advocates, and the managed care industry to develop a coordinated quality oversight system to reduce duplicative or conflicting efforts and that has an emphasis on demonstrable and measurable improvement.
- Initiatives to improve accountability by requiring uniform collection and reporting of data to allow assessment of plan performance and to facilitate comparisons among plans, such as the Health Plan Employer Data and Information Set (HEDIS 3.0).
- Projects to enhance the role of Medicare Peer Review Organizations (PROs) in evaluating and improving managed care plan quality, including the development and testing of a minimum set of performance evaluation measures and quality improvement projects developed through collaboration between PROs and the managed care industry.

Second, we anticipate that many new M+C organizations will be offered by organizations currently participating as Medicare risk contractors. While we acknowledge that many organizations have not developed the capacity to fully meet the pre-BBA requirements, we believe that this regulation does not create substantially new demands for building new administrative and information systems necessary to meet the quality assessment and performance improvement requirements for M+C products, as such organizations already are subject to similar requirements as section 1857 contractors. Moreover, we will build into the contract process a gradual phase-in of the number of focus areas for which a plan must demonstrate improvement to allow sufficient time for a plan to implement and conduct well-designed improvement projects.

Third, we anticipate that many organizations seeking to offer M+C products will have had to invest in administrative and information systems to meet the requirements of other purchasers and State regulators, diminishing burdens this regulation might otherwise have imposed. This is true even for provider-sponsored organizations that seek a federal waiver from state solvency requirements, as such entities are still subject to other state requirements, including a state's quality assessment and improvement requirements.

We have built on efforts in other sectors in developing these quality assessment and performance improvement requirements in order to minimize the burden that these activities place on plans. (GAO, September 1996; NCQA, 1997), such as:

- Many employers and cooperative group purchasing groups and some States already require that organizations be accredited by the National Committee on Quality Assurance, the Joint Commission on Accreditation of Healthcare Organizations, the American Healthcare Accreditational Commission, or other independent bodies.
- Many also require that organizations report their performance on HEDIS, FACCT, or other measures and conduct enrolled surveys using the CAHPS or other instruments. For example, NCQA estimates that more than 90 percent of plans are collecting some or all of HEDIS data for their commercial population. (NCQA, 1997)
- States have heightened their regulatory efforts through insurance or licensing requirements, and the National Association of Insurance Commissioners has developed model acts on network adequacy, quality assessment and improvement, and utilization review.

Another important mechanism in avoiding duplication of effort and unnecessary administrative burdens with respect to internal quality assurance requirements is the ''deemed'' status afforded organizations for each standard that is accredited by a national, private accrediting organization.

Fourth, we have worked closely with private-sector leaders in health plan performance and quality measurement to avoid duplication of effort and promote standardization in measurement approaches. (GAO, September 1996) For example, we convened advisory groups of managed care organizations, State and Federal purchasers and regulators, beneficiary advocates, and experts in mental health and substance abuse services and relied heavily on the insight and expertise of these groups in refining standards and guidelines.

Fifth, measuring and reporting plan- and provider-specific information will allow plans and networks to compare themselves to competitors, track their own performance over time, and so drive their own internal quality improvement programs. (Palmer, 1997). Moreover, plans will have added incentives to initiate performance improvement projects that will lead to more cost-effective delivery of health care services, such as influenza immunization outreach efforts which lead to lower complications and treatment of influenza-related conditions or improving access to primary care to reduce inappropriately frequent use of the emergency room by enrollees. This regulation allows plans the freedom to select its own particular topics for measurement and improvement so that each plan can conduct projects relating to aspects of care and services that are significant for its own population.

Although the quality standards under this regulation are not substantially

different from requirements already in place, we recognize that some M+C organizations may need to invest in administrative and/or information systems necessary to comply with the existing as well as the M+C standards. Additionally, while some plans may be tempted to invest their resources into the areas in which they must measure and demonstrate improved performance at the expense of other parallel quality initiatives, we have designed the quality assessment and performance improvement requirements under this regulation to be as flexible as possible and encourage plans to work with HCFA in developing long-range goals for projects.

Our role in overseeing compliance with the quality standards interrelates with our efforts to sponsor an annual information campaign that coincides with the open enrollment period for M+C organizations and is an important augmentation to those efforts. These efforts are designed to ensure that all organizations in the M+C program have the organizational structure and operational capacity to provide quality health care to Medicare beneficiaries and to ensure that beneficiaries have accurate information on quality to guide their health plan selections.

F. Conclusion

We expect that this rule overall will have a positive impact on the Medicare program, Medicare beneficiaries, providers, rural providers and suppliers, and entities that have not previously contracted with us. However, some current managed care contractors will experience a decrease in the capitated payments they otherwise would have received without passage of the BBA, possibly resulting in reduced benefits for Medicare enrollees. States will also have to develop mechanisms to license new risk bearing entities known as provider sponsored organizations after 3-year waivers.

VI. Collection of Information Requirements

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320. The Agency cannot reasonably comply with the normal clearance procedures because of the statutory requirement, as set forth in section 1856 of Balanced Budget Act of 1997, to implement these requirements on June 1, 1998.

HCFA is requesting OMB review and approval of this collection within 11 working days, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individual designated below, within 10 working days of publication of this document in the **Federal Register**.

During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.5.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements summarized and discussed below.

Application Requirements (§ 422.6)

In order to obtain a determination on whether it meets the requirements to become an M+C organization and is qualified to provide a particular type of M+C plan, an entity, or an individual authorized to act for the entity (the applicant) must complete an application, in the form and manner required by HCFA, including all of the requirements set forth in § 422.6.

In order to contract with us under the M+C program, organizations are required to complete an application to demonstrate their capability of carrying out the requirements of the Medicare program. Completing an application requires the capability of organizations to adhere to Medicare program guidelines and demonstrate to HCFA by in-house documentation that such capability exists. In prior years, applicants were required to complete applications forms (HCFA 901–903) to obtain a Medicare contract under section 1876 of the program. The application having OMB clearance #0938–0470 estimated that approximately 100 hours would be required to complete an application. We believe the new applications are quite similar and therefore estimate that 100 hours will be required to complete an application under the Medicare + Choice program. We project approximately 100 applications a year requiring 10,000 hours of time by all applicants on an annual basis.

Eligibility To Elect an M+C Plan (§ 422.50)

A beneficiary must complete and sign an election form and gives information required for enrollment.

The burden associated with this requirement is the time it takes for a beneficiary to complete an enrollment form. The enrollment form varies for each organization, but similar identifying information is collected. It is estimated that it will take 2,000,000 beneficiaries (based on 2,012,025 enrollments in calendar year 1997) 10 minutes for an annual burden of 20,000,000 minutes = 333,000 hours.

Continuation of Enrollment (§ 422.54)

An M+C organization that wishes to offer a continuation of enrollment option must submit their marketing materials to HCFA for approval, which meet the requirements set forth in this section, that describe the option and the M+C organization's assurances of access to services as set forth in this section and, an M+C organization that offers a continuation of enrollment option must convey all enrollee rights conferred under this rule.

The burden associated with this requirement is captured below in § 422.64.

Election Process (§ 422.60)

The election form must be completed and signed by the M+C eligible individual beneficiary (or the individual who will soon become entitled to Medicare benefits) and include authorization for disclosure and exchange of necessary information between HCFA and the M+C organization.

The burden associated with this requirement is captured above in the § 422.50 discussion.

The M+C organization must file and retain M+C plan election forms for the period specified in HCFA instructions, and submit beneficiary M+C plan and optional supplemental benefit elections to HCFA.

The burden associated with this requirement is the time required for each organization to perform record

keeping on each application filed. It is estimated that it will take each organization 5 minutes for each of 2,000,000 beneficiaries (based on 2,012,025 enrollments in calendar year 1997). The total annual burden is estimated at 10,000,000 minutes = 167,000 hours. On average, M+C organizational level burden is 167,000/450 (100 new/350 current) = 371 annual hours. In addition, it is estimated to take each M+C organization 4 hours per month to electronically submit a subset of beneficiary M+C plan and optional supplemental benefit election information to HCFA, for a total annual burden of 21,600 hours.

The M+C organization must give the beneficiary prompt written notice of acceptance or denial in a format specified by HCFA that meets the requirements set forth in this section.

The burden associated with each organization providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1 minute per application processed. The annual total burden is estimated at 2,000,000 minutes = 33,000 hours. On average, M+C organizational level burden is 33,000/450 (100 new/350 current) = 73 annual hours.

Within 30 days from receipt of the election form (or from the date a vacancy occurs for an individual who was accepted for future enrollment), the M+C organization must transmit the information necessary for HCFA to add the beneficiary to its records as an enrollee of the M+C organization.

The burden associated with electronic submission of information to HCFA is estimated at 1 second per application processed, for an annual burden of 2,000,000 minutes = 33,000 hours. On average, M+C organizational level burden is 33,000/450 (100 new/350 current) = 73 annual hours.

Election of Coverage Under an M+C Plan (§ 422.62)

Except as provided in paragraph (d)(2)(ii) of § 422.62, an individual may disenroll from an M+C MSA plan only during an annual election period or the special election period described in paragraph (b) of this section. However, an individual who elects an M+C MSA plan during an annual election period and had never before elected an M+C MSA plan may revoke that election, no later than December 15 of that same year, by submitting to the organization that offers the M+C plan a signed and dated request in the form and manner prescribed by HCFA or by filing the appropriate disenrollment form through other mechanisms as determined by HCFA.

The burden associated with this requirement is the time required for each beneficiary to complete a disenrollment form. It is estimated that about 5 percent of the maximum number of beneficiaries permitted to choose an MSA (390,000) would disenroll (19,500) and each disenrollment form would take 4 minutes to complete, for an annual burden of 78,000 minutes = 1,300 hours.

Information About the M+C Program (§ 422.64)

Each M+C organization must provide, on an annual basis and in a format and using standard terminology that may be specified by HCFA, the information necessary that meets the general and content requirements set forth in § 422.6, to enable HCFA to provide to current and potential beneficiaries the information they need to make informed decisions with respect to the available choices for Medicare coverage.

The burden associated with this requirement is the time required for the organization to provide the information to HCFA. It is estimated that it will take 450 (100 new/350 current) organizations 12 hours for an annual burden of 5,400 hours. In addition, it is estimated that on an annual basis it will take 4 hours for an estimated 50 organizations to modify and submit their revised materials to HCFA for review for a annual burden of 200 hours.

Coordination of Enrollment and Disenrollment Through M+C Organizations (§ 422.66)

An individual who wishes to elect an M+C plan offered by an M+C organization may make or change his or her election during the election periods specified in § 422.62 by filing the appropriate election form with the organization or through other mechanisms as determined by HCFA.

An individual who wishes to disenroll from an M+C plan may do so by (1) electing a different M+C plan by filing the appropriate election form with the M+C organization or through other mechanisms as determined by HCFA, (2) submitting a signed and dated request for disenrollment to the M+C organization in the form and manner prescribed by HCFA or, (3) filing the appropriate disenrollment form through other mechanisms as determined by HCFA.

The burden associated with electing a different plan is included in 422.50. The burden associated with disenrolling is the time to complete a disenrollment form. It is estimated that 720,000 disenrollments (based on the number of disenrollments in calendar 1997) will take 2 minutes each for an annual burden of 1,440,000 minutes = 2,400 hours. On average, M+C organizational level burden is 2,400/450 (100 new/350 current) = 5 annual hours.

The M+C organization must submit each disenrollment notice to HCFA promptly.

The burden associated with electronic submission of information to HCFA is estimated at 1 second per disenrollment processed, for an annual burden of 1,200 minutes = 20 hours.

On average, M+C organizational level burden is 1,200/450 (100 new/350 current) = 3 annual hours.

In the case of a plan where lock-in applies, the M+C organization must provide the enrollee with a statement explaining that he or she remains enrolled until the effective date of disenrollments, and until that date, neither the M+C organization nor HCFA pays for services not provided or arranged for by the M+C plan in which the enrollee is enrolled.

The burden associated with each organization providing the beneficiary prompt written notice of disenrollment and lock-in, produced by an automated system, is estimated at 1 minute per disenrollment processed, for an annual burden of 720,000 minutes = 1,200 hours. On average, M+C organizational level burden is 1,200/450 (100 new/350 current) = 3 annual hours.

The M+C organization must file and retain disenrollment requests for the period specified in HCFA instructions.

The burden associated for each disenrollment request is the time required for each organization to perform recordkeeping on each disenrollment request filed. It is estimated that it will take 5 minutes for 720,000 disenrollments processed for an annual burden of 3,600,0000 minutes = 60,000 hours. On average, M+C organizational level burden is 6,000/450 (100 new/350 current) = 13 annual hours.

Disenrollment by the M+C Organization (§ 422.74)

If the disenrollment is for any of the reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(3) of § 422.74, that is, other than death or loss of entitlement to Part A or Part B, the M+C organization must give the individual a written notice of the disenrollment with an explanation of why the M+C organization is planning to disenroll the individual. The notice must be mailed to the individual before submission of the disenrollment notice to HCFA and include an explanation of the individual's right to a hearing under the

M+C organization's grievance procedures.

There is a burden associated with the requirement for the organization to notify the beneficiary about an involuntary disenrollment, and to separately notify the beneficiary of the effective date of the disenrollment. It is estimated that less than 100 such notices will be issued and that each notice will take 1 minute for an annual burden of less than 100 minutes = or less than 1.5 hours.

A M+C organization may disenroll an individual from the M+C plan for failure to pay any basic and supplementary premiums if the M+C organization sends a written notice of nonpayment to the enrollee within 20 days of the date that the delinquent charges were due stating that nonpayment of premiums will not automatically result in disenrollment and information about the lock-in requirements of the M+C plan.

There is a burden associated with the requirement for the organization to notify the beneficiary and it is estimated that less than 500 of these requests occur annually at 1 minute per notification, resulting in an estimated burden of 500 minutes, or approximately 80 hours.

A M+C organization may disenroll an individual from the M+C plan if the individual's behavior is disruptive, unruly, abusive, or uncooperative to the extent that his or her continued enrollment in the plan seriously impairs the M+C plan's ability to furnish services to either the particular individual or other individuals enrolled in the plan. The M+C organization must document the enrollee's behavior, its own efforts to resolve any problems, and any extenuating circumstances, as described in paragraphs (d)(2)(i) through (d)(2)(iii) of this section. And, a M+C organization must submit documentation related to the proposed disenrollment and any information submitted by the beneficiary, to HCFA for review to determine whether the M+C organization has met the disenrollment requirements.

The burden associated with this requirement is the time for the organization to document the behavior of the beneficiary and document the efforts of the organization to resolve any problems and provide information to HCFA concerning the involuntary disenrollment request. The burden reflects documentation and transmission of documentation to HCFA by the managed care plans. It is estimated that less than 100 such requests occur annually (based on estimate of regional office collection of such information), and it is estimated that each request will take 1 hour to manually collect the data and 15 minutes to transmit the data to HCFA, for a burden of 125 hours.

A M+C organization must report to the Office of the Inspector General of the DHHS any disenrollment based on fraud or abuse by the individual.

There is a burden associated with the requirement for the organization to report to the Office of the Inspector General any disenrollment based on fraud or abuse by the individual. It is estimated that only 1% of all involuntary disenrollments, or 10 involve fraud or abuse, and the reporting burden would be 1 minute each, for a total burden of less than 1 hour.

If a M+C organization terminates or is terminated or the service area or continuation area are reduced with respect to all M+C enrollees in the area in which they reside, the M+C organization must give each Medicare enrollee a written notice of the effective date of the plan termination or area reduction and a description of alternatives for obtaining benefits under the M+C program. The notice must be sent before the effective date of the plan termination or area reduction.

The burden associated with this requirement is captured below in § 422.506.

Approval of Marketing Materials and Election Forms (§ 422.80)

At least 45 days before the date of distribution the M+C organization must submit any marketing material or election form to HCFA for review. The materials must be in a format and using standard terminology specified by HCFA, that meet the requirements specified in this section.

The burden associated with this requirement is captured above in § 422.64.

A M+C organization must notify the general public of its enrollment period (whether time-limited or continuous) in an appropriate manner, through appropriate media, throughout its enrollment area.

We anticipate notification to the general public would be through a general circulation newspaper and would require 8 hours of burden per organization to modify their enrollment period bulletin and seek publication in a local newspaper, for an annual burden of 3,600 hours.

Special Rules for Point of Service Option (§ 422.105)

M+C organizations must maintain written rules on how to obtain health benefits through the POS benefit. While the maintenance of written rules is a recordkeeping requirement subject to the PRA, the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (b)(3).

The M+C organization must provide to beneficiaries enrolling in a plan with a POS benefit an ''evidence of coverage'' document, or otherwise provide written documentation, that specifies all costs and possible financial risks to the enrollee, including the requirements set forth in (d)(2)(i) through (d)(2)(iv) of this section.

The burden associated with this requirement is captured above in § 422.64.

An M+C organization that offers a POS benefit must report data on the POS benefit in the form and manner prescribed by HCFA.

The special rules for M+C organizations offering a POS benefit as stipulated in § 422.105 requires that M+C organizations provide to HCFA POS data relating to the utilization of the POS benefit by plan members. This is not a new data requirement since M+C organizations that offer a POS benefit would need to have this data in the normal course of business in order to pay POS claims. We estimate that providing this data to HCFA would require 1 hour per quarterly submission. Thus, the annual burden would be 1 hour $\times$ 4 = 4 hours per MCO in providing the required POS data.

Disclosure Requirements (§ 422.111)

An M+C organization must disclose the information specified in § 422.64 and in paragraph (b) of § 422.111 to each enrollee eligible for or electing an M+C plan it offers. The information must be in clear, accurate, and standardized form, and provided at the time of enrollment and at least annually thereafter. The burden associated with this requirement is captured above in § 422.64.

If an M+C organization intends to change its rules for an M+C plan, it must submit the changes for HCFA review under the procedures of § 422.80. The burden associated with this requirement is reflected in § 422.80 above.

The plan must also give notice to all enrollees 30 days before the intended effective date of the changes. The burden associated with this requirement is reflected above in § 422.80.

The M+C organization must make a good faith effort to provide written notice of a termination of a contracted provider within 15 working days of receipt or issuance of a notice of termination, as described in

§ 422.204(c)(4), to all enrollees who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all enrollees who are patients of that primary care professional must also be notified.

HCFA has no basis to calculate the burden impact imposed by these requirements. Therefore, we explicitly seek comment on the impact of this notification requirement.

Access to Services (§ 422.112)

In the case of involuntary termination of an M+C plan or specialist(s) for a reason other than for cause, the M+C organization must inform beneficiaries of their right to maintain access to specialists and provide the names of other M+C plans in the area that contract with specialists of the beneficiary's choice, as well as an explanation of the process the beneficiary would need to follow should he or she decide to return to original Medicare.

The requirements imposed by this section would be pursuant to an administrative action and therefore are exempt from the PRA as defined in 5 CFR 1320.4.

An M+C plan seeking a service area expansion must demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served. The burden associated with meeting this requirement is captured above in 422.6.

An M+C plan must demonstrate to HCFA that its providers are credentialed through the process set forth at § 422.204(a). The burden associated with meeting this requirement is captured above in 422.6.

Plans must have procedures approved by HCFA for (1) identification of individuals with complex or serious medical conditions; (2) assessment of those conditions, including medical procedures to diagnose and/or monitor them on an ongoing basis; and (3) establishment of a treatment plan appropriate to those conditions, with an adequate number of direct access visits to specialists to accommodate the treatment plan. Treatment plans must be time-specific and updated periodically by the PCP.

Plans must also; (1) establish written standards for the timeliness of access to care and member services that meet or exceed standards established by HCFA, (2) continuously monitor and document the timely access to care and member services within a plan's provider network to ensure compliance with these standards, and take corrective action as necessary, (3) establish written policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations, and (4) ensure that providers consider and document beneficiary input into the provider's proposed treatment plan.

Plans must maintain written procedures to ensure that; (1) the M+C organization and its provider network have the information required for effective and continuous patient care and quality review, including procedures to ensure that, each provider, supplier, and practitioner furnishing services to enrollees maintains an enrollee health record in accordance with standards established by the M+C organization, taking into account professional standards; appropriate and confidential exchange of information among provider network components, (2) written procedures to ensure that enrollees are informed of specific health care needs that require follow-up and receive, as appropriate, training in self-care and other measures they may take to promote their own health; and (4) documentation demonstrating that systems to address barriers to enrollee compliance with prescribed treatments or regimens.

HCFA's believes these requirements are reasonable and customary business practices and the burden associated with these requirements is exempt from the PRA as defined in 5 CFR 1320.3(b)(2). Therefore, we are assigning one token hour of burden for these requirements. HCFA invites comment on the burden estimate associated with these requirements.

Confidentiality and Accuracy of Enrollee Records (§ 422.118)

For any medical records or other health and enrollment information it maintains with respect to enrollees, an M+C organization must establish and maintain procedures set forth in (a) through (c) of this section.

While the maintenance of health records is a recordkeeping requirement subject to the PRA, we believe the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and (b)(3), and assigning 1 token hour of burden for this requirement. We solicit comment on the burden associated with this requirement.

Information on Advance Directives (§ 422.128)

Each M+C organization must maintain written policies and procedures that meet the requirements for advance directives, as set forth in 43 CFR part 489 subpart I.

An M+C organization must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care by or through the M+C organization.

An M+C organization must provide written information to those individuals with respect to the requirement set forth in this section.

These requirements are identical to the requirements currently approved under OMB# 0938–0610, with an expiration date of July, 31, 1999. Since the currently approved requirements encompass a larger universe of provider types then just managed care organizations it is difficult to estimate the burden on the M+C organizational level. However, the per beneficiary encounter burden is estimated to be 3 minutes. In the near future, HCFA will revise this collection to capture this new provider type and resubmit the collection to OMB for approval.

Protection Against Liability and Loss of Benefits (§ 422.132)

Each M+C organization must adopt and maintain arrangements satisfactory to HCFA to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the M+C organization. The burden associated with demonstrating this requirement is captured below under § 422.306.

Each M+C organization must have an insolvency protection plan that provides for continuation of benefits. Each plan must submit a insolvency plan to HCFA for approval. The reporting requirements are similar to the insolvency plan reporting requirements submitted by 1876 plans. The burden associated with completing and submitting an insolvency plan is estimated to be 40 hours per plan on an annual basis. Therefore, the total annual burden associated with this requirement is 18,000 hours (40 hours x 450 plans (100 new/350 current)). In the near future, HCFA will revise this collection to capture this new provider type and resubmit the collection to OMB for approval.

Quality Assessment and Performance Improvement Program (§ 422.152)

The organization offering the plan must measure performance under the

plan, using standard measures required by HCFA, and report its performance to HCFA.

All Medicare+Choice organizations and an organization offering an M+C non-network MSA plan or an M+C private fee-for-service plan will be required to measure performance under their plans, using standard measures required by HCFA, and report their performance to HCFA. Reporting will be required annually. The standard measures that will be required will most likely be those already captured in HEDIS and CAHPS, approved under OMB # 0938–0701. The currently approved annual per plan burden is estimated to be 400.53 hours. Therefore, the total burden associated with this requirement is 180,239 hours (400.53 hours × 450 plans (100 new/350 current)). In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

The organization must report the status and results of each performance improvement project to HCFA as requested.

All Medicare+Choice organizations offering coordinated care plans will be required to undertake performance improvement projects relative to those plans. Each organization must report the status and results of each project to HCFA as requested. We expect that, in any given year, each organization will complete two projects, and will have two others underway, relative to each plan. We expect that we will request the status and results of each organization's projects annually. We estimate that it will take an organization 5 hours to prepare its report for each project. Therefore, we estimate that the total annual hours involved per plan to be 20 and an overall annual burden for all plans of 9,000 hours.

For all types of plans that it offers, an organization must: (1) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program, (2) Ensure that the information it receives from providers of services is reliable and complete, and (3) Make all collected information available to HCFA.

All M+C organizations must maintain a health information system, and must make all collected information available to HCFA. The requirement guarantees our access to organization information: it does not impose an obligation for routine organization submission of information. At this time, we do not anticipate requesting information other than that relating to the standard measures and performance improvement projects discussed above.

External Review (§ 422.154)

Except as provided in paragraph (c) of § 422.154, each M+C organization must, for each M+C plan it operates, have an agreement that meets the provisions of this section, with an independent quality review and improvement organization (review organization) approved by HCFA to perform functions of the type described in 42 CFR part 466 of this chapter.

Most M+C organizations must have an agreement with a review organization approved by HCFA to perform functions of the type described in 42 CFR part 466. A similar requirement already exists for Medicare contracting HMOs, at § 466.72. The burden estimate prepared for OMB submission #0938–0445 would also apply to the new requirement. The currently approved burden associated with this requirement on the organizational level is 10 hours every three years.

In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

Compliance Deemed on the Basis of Accreditation (§ 422.156)

An M+C organization deemed to meet Medicare requirements must: (1) Submit to surveys by HCFA to validate its accreditation organization's accreditation process, and (2) authorize its accreditation organization to release to HCFA a copy of its most recent accreditation survey, together with any survey-related information that HCFA may require (including corrective action plans and summaries of unmet HCFA requirements).

The burden associated with this requirement is captured below in § 422.158.

Accreditation Organizations (§ 422.157)

An accreditation organization approved by HCFA must undertake the following activities on an ongoing basis: (1) Provide to HCFA in written form and on a monthly basis all of the information required in paragraphs (c)(1)(i) through (c)(1)(v) of § 422.157, (2) Within 30 days of a change in HCFA requirements, submit to HCFA all of the information required in paragraphs (c)(2)(i) through (c)(2)(iii) of § 422.157, (4) Within 3 days of identifying, in an accredited M+C organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give HCFA written notice of the deficiency, and (5) Within 10 days of HCFA's notice of withdrawal of approval, give written notice of the withdrawal to all accredited M+C organizations. The burden associated with this requirement is captured below in § 422.158.

Procedures for Approval of Accreditation as a Basis for Deeming Compliance (§ 422.158)

A private, national accreditation organization applying for approval must furnish to HCFA all of the information and materials referenced in this section. However, when reapplying for approval, the organization need furnish only the particular information and materials requested by HCFA.

The BBA allows HCFA to deem that a M+C organization meets certain Medicare requirements if that organization is accredited by an accreditation organization approved by HCFA. We expect that four national accreditation organizations will eventually be approved. The application and oversight procedures that we have developed for deeming in the managed care arena mirror those already in place in the fee-for-service arena as currently approved under OMB # 0938–0690. Therefore, much of the burden estimate prepared for the fee-for-service deeming regulations in 42 CFR part 488, Subpart A, would also apply here. The initial application burden associated with obtaining deeming authority is 96 hours every six years. Since we anticipate that four organizations will apply, the total burden is 386 hours over a six year period. The ongoing burden of supplying HCFA with data on the status of its deemed facilities is estimated to be 48 annual hours per deeming organization for a total annual burden of 192 hours. In the near future HCFA will resubmit this collection to OMB for approval of deeming in the managed care arena use.

Participation Procedures (§ 422.202)

An M+C organization that operates a coordinated care plan or network MSA must provide for the participation of individual health care professionals and of the management and members of groups through reasonable written procedures that include the following; (1) written notice of rules of participation such as terms for payment, utilization review, quality improvement programs, credentialing, data reporting, confidentiality, guidelines or criteria for the furnishing of particular services, and other rules related to administrative policy, (2) written notice of material changes in participation rules before the changes are put into effect, (3) written notice of participation decisions that are adverse to health care professionals, (4) a process for appealing adverse

decisions, including the right of physicians and other health care professionals to present information and their views on the decision.

The M+C organization must maintain documentation demonstrating that: (1) practice guidelines and utilization management guidelines meet the requirements of (1)(i) through (iv) of this section, (2) the guidelines have been communicated to providers and, as appropriate, to enrollees, (3) decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines, and (4) an M+C organization that operates an M+C plan through subcontracted physician groups or other subcontracted networks of health care professionals provided that the participation procedures in this section apply equally to physicians and other health care professionals within those subcontracted groups.

The burden associated with these requirements is the time required to maintain documentation demonstrating that the requirements have been met and, as necessary, the time necessary to communicate the guidelines to providers and enrollees. HCFA believes that these requirements are reasonable and customary business practices and the burden of meeting these requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2). Therefore, we are assigning one token hour of burden to these requirements. We explicitly solicit comments on the burden associated with meeting these requirements.

Participation Contracts: Requirements and Prohibitions (§ 422.204)

An M+C organization that operates a coordinated care plan or network MSA plan that provides benefits through contracting health care professionals must provide notice to contracting professionals when the organization denies, suspends, or terminates their agreement with the professional and include (1) the reason for the action, (2) the standards and the profiling data the organization used to evaluate the professionals, (3) the numbers and mix of health care professionals needed for the organization to provide adequate access to services, and (4) the professional's right to appeal the action and the timing for requesting a hearing. This is a new requirement.

The burden associated with this requirement is the time required for organization to prepare a written notification of the denial, suspension, or termination of their agreement with the organization. In discussions with HCFA plan managers, it was predicted that .5 percent of all organizations (approximately 2 organizations) would find it necessary to take such action for about 1 percent of their contracted professionals within a single year and if the organization was already established and doing business. The range of number of contracted professionals extends from 3 contracted professionals to 67,000. Excluding outliers on both ends of the range, we estimate that an organization contracts with an average of 3,000 health care professionals. Using an estimate of 10 minutes per instance to generate and furnish a notice of such action, the total burden on known contractors (350) would be 2 organizations * 30 * 10 minutes = 600 minutes or 10 hours annually.

In addition, HCFA expects to receive approximately 100 additional applications for contracts with new entities to be processed in 1998 for 1999. For organizations creating new networks, they would probably all have at least one instance of denial the first year affecting approximately 1 percent of the number of contracting professionals. Using an estimate of 10 minutes per instance to generate and furnish a notice of such action, the total burden on new contractors would be 100 organizations * 30 * 10 minutes = 30,000 minutes or 500 hours. The total burden with current applications and expected applications for contracts would be 510 hours annually.

The number of new organizations is expected to increase by 100, on an annual basis creating an expected burden for current contracts [350(*.005(organization-rounded to the nearest whole number) *30*10)/60 =]10 hours + new contracts [100*30*10 /60 =]500 hours = 510 hours.

An M+C organization is required to notify any licensing or disciplinary bodies or other appropriate authorities when it suspends or terminates a contract with a health care professional because of deficiencies in the quality of care provided by the professional.

The burden associated with this requirement is the time required for the organization to prepare a written notification to the appropriate authorities. No exact data is available to estimate how often this situation might occur. HCFA estimates that this situation might occur in 3 percent of the M+C organizations once during an annual period. The amount of time estimated to prepare the written notification is 10 minutes. The annual burden associated with this requirement is estimated to be [450 * .03 * 1 *10/ 60] = 2.25 hours.

Interference With Health Care Professionals' Advice to Enrollees Prohibited (§ 422.206)

Section 422.206 prohibits the M+C organization from restricting the provision of treatment advice by health care professionals to enrollees. However, the prohibition against interference is not construed as requiring counseling by a professional or a referral to a service by that professional, if there is an objection based on moral and religious grounds. Section 422.206 implements a new disclosure requirement and requires M+C organizations to notify HCFA during the application process, and later to all current and prospective enrollees, through appropriate written means, if the organization has such a conscience protection policy regarding counseling in effect or if the policy is changed subsequent to the application. The expected number of M+C organizations exercising this option is not expected to exceed 10 in any given year. The amount of burden imposed in the application process, which is captured in the application burden and in the preparation of the contents of the subscriber agreement or member handbook or a subsequent written notice to enrollees is reflected above in § 422.6 and § 422.64.

Physician Incentive Plans: Requirements and Limitations (§ 422.208)

An M+C organization must conduct periodic surveys of current and former enrollees where substantial financial risk exists.

The burden associated with this requirement is captured below in § 422.210.

Disclosure of Physician Incentive Plans (§ 422.210)

Each M+C organization must provide to HCFA descriptive information about its physician incentive plan in sufficient detail to enable HCFA to determine whether that plan complies with the requirements of § 422.208. Reporting should be on the HCFA PIP Disclosure Form (OMB No. 0938–0700). An M+C organization must disclose annually to HCFA the physician incentive arrangements that are effective at the start of each year.

Sections 422.208 and 422.210 require disclosure of physician incentive plan information to HCFA or to States and to Medicare beneficiaries and the enrollee surveys required when plans put providers at substantial risk. This collection of information, Incentive Arrangement Form HCFA–R–201 and supporting regulations, used to monitor

physician incentive plans on an annual basis, is approved under OMB # 0938–0700. In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

Special Rules for M+C Private Fee-for-Service Plans (§ 422.216)

The M+C organization must make information on its payment rates available to providers that furnish services that may be covered under the M+C private fee-for-service plan.

We expect the M+CPFFS plan to provide written information to contracting providers and to make the information available via a website or toll free number to noncontracting providers who inquire. 50 M+CPFFS plans (estimate of M+CPFFS plans in out years; in first year we may have none) will be required to provide 20,000 annual responses (about 1 million providers nationwide divided by 50 M+CPFFS plans) at an estimated 5 minutes per disclosure (average of phone calls, website time, mailing time for hard copies to contracting providers) for a total annual burden of 1,667 hours per provider and an overall annual burden of 83,350 hours.

An M+C organization that offers an M+C fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section. Specifically, an M+C organization that offers an M+C private fee-for-service plan must monitor the amount collected by non-contract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section. The M+C organization must develop and document violations specified in instructions and must forward documented cases to HCFA.

M+C private fee-for-service plans must investigate and send to HCFA documentation of excessive charges by providers. It is estimated that 50 M+C private fee-for-service plans will have 10 cases per year, at 20 hours per case (to contact the enrollee who complained, acquire and review documents, contact the provider, prepare report to HCFA). Therefore, the total burden associated with this requirement is 10 cases × 20 hours = 200 annual hours per plan, for a total annual burden of 10,000 hours.

An M+C organization that offers an M+C private fee-for-service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing.

This requirement is akin to the Medicare EOMB or summary statement and must be furnished on a regular basis for every claim paid or denied by the M+C private fee-for-service plan. It is estimated that 3 million notices will be disseminated by M+C private fee-for-service plans. This estimate is determined by; multiply 5000 enrollees per plan by 12 (one notice per month) or 60,000, multiplied by an estimated 50 plans for a total of 3 million notices. At an estimated 3 minutes of burden per notice, the total burden is 9 million minutes or 150,000 burden hours. On a plan level the average annual burden is estimated to be 3,000 hours.

In its terms and conditions of payment to hospitals, organization the hospital is required, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than $500: (1) Notice that balance billing is permitted for those services; (2) a good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and (3) the amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

It is estimated that 20,000 of 25,000 estimated hospitalizations will require these notices. The $500 tolerance will be exceeded each time the plan payment rate for the inpatient stay would exceed $3333.33—which is probably almost all of them—if the plan lets the hospital balance bill. At 5 minutes of burden per notice times 20,000 annual notices, the total burden is 100,000 minutes or 1,667 hours of burden.

Encounter Data (§ 422.257)

Each M+C organization must submit to HCFA (in accordance with HCFA instructions) all data necessary and as stipulated under this section to characterize the context and purpose of each encounter between a Medicare enrollee and a provider, supplier, physician, or other practitioner.

The Act requires that the collection of inpatient hospital data for discharges beginning on or after July 1, 1997 and allows the collection of other data no earlier than July 1, 1998. The statutory language is clearly tied to the creation of risk-adjusted payment rates, as defined at § 422.256 (c) and (d) of this rule. Requirements concerning collection of encounter data apply to M+C organizations with respect to all their M+C plans, including medical savings accounts (MSAs) and private fee-for-service plans.

M+C organizations must submit data as follows: (1) Beginning on a date determined by HCFA, inpatient hospital care data for all discharges that occur on or after July 1, 1997.

These requirements are approved under OMB # 0938–0711, with an expiration date of July 31, 1998. The burden associated with submitting data for inpatient hospital care data for all discharges that occur on or after July 1, 1997, is currently .5 minutes per EMC bill and 1 minute per hard copy bill. Although there are currently three options for submitting bills, on average the total annual burden per plan is 46.5 hours, with an overall burden of annual 32,833 hours.

HCFA will provide advance notice to M+C organizations to collect and submit: (1) Physician, outpatient hospital, SNF, and HHA data beginning no earlier than October 1, 1999; and (2) all other data HCFA deems necessary beginning no earlier than October 1, 2000. We estimate the following burden for each category based on a projection of 15 seconds per claim: Physician: 72 million claims = 300,000 hours Outpatient hospital: 12 million claims = 50,000 hours HHA, Hospice, SNF: 2.4 million claims = 10,000 hours All other: 24 million claims = 100,000 hours

We will implement this provision by providing for direct transmission from the provider to HCFA with common PC-based technology. It should be noted that prior to implementing the requirement for M+C organizations to collect and submit physician, outpatient hospital, SNF, and HHA data HCFA will amend OMB # 0938–0711 and seek OMB PRA approval. As part of the PRA process the public will be given several opportunities to comment, via **Federal Register** notification, on the proposed collection prior to OMB approval and implementation.

M+C organizations and their providers and practitioners will be required to submit medical records for the validation of encounter data, as prescribed by HCFA.

Currently HCFA plans on implementing this requirement pursuant to an administrative action or audit, based on data submitted to HCFA or one of its agents. Therefore, these requirements are currently not subject to the PRA as defined in 5 CFR 1320.4.

However, if HCFA were to implement these requirements on a prospective basis, as part of a program oversight activity, we will amend OMB # 0938–0711 and seek OMB PRA approval. As part of the PRA process the public will be given several opportunities to comment, via **Federal Register** notification, on the proposed collection prior to OMB approval and implementation.

Special Rules for Beneficiaries Enrolled in M+C MSA Plans (§ 422.262)

An entity that acts as a trustee for an M+C MSA must: (1) Register with HCFA, (2) certify that it is a licensed bank, insurance company, or securities broker, or other entity qualified, under sections 408(a)(2) or 408(h) of the IRS Code, to act as a trustee, (3) agree to comply with the M+C MSA provisions of section 138 of the IRS Code of 1986; and (4) Provide any other information that HCFA may require.

An M+C organization offering an M+C MSA plan will have to register with HCFA for each beneficiary enrolled. This will require a short form that would take no more than five minutes to fill out. The Act limits the number of MSA enrollees to 390,000; therefore, with maximum participation, registration with HCFA would take 32,500 hours. (i.e., 390,000 registration forms at 5 minutes each.)

Items 2 and 3, above, are IRS requirements and entail no reporting requirements for HCFA. Under item 4, above, we anticipate no further M+C MSA reporting requirements at this time.

Special Rules for Hospice Care (§ 422.266)

An M+C organization that has a contract under Subpart K of part 422 must inform each Medicare enrollee eligible to elect hospice care under section 1812(d)(1) of the Act about the availability of hospice care (in a manner that objectively presents all available hospice providers, including a statement of any ownership interest in a hospice held by the M+C organization or a related entity) if: (1) A Medicare hospice program is located within the organization's service area, or (2) It is common practice to refer patients to hospice programs outside that area.

At present, one-twentieth of one percent (three thousand) of Medicare managed care enrollees have elected the hospice option. We estimate that informing beneficiaries about their hospice choices would take about ten minutes. For three thousand beneficiaries, this represents a total burden of 500 hours. On a organizational level the annual burden would be 500 hours / 450 M+C organizations (100 new/350 current) = 1.2 annual burden hours per entity.

Submission of Proposed Premiums and Related Information (§ 422.306)

Not later than May 1 of each year, each M+C organization and any organization intending to contract as an M+C organization in the subsequent year must submit to HCFA, in the manner and form prescribed by HCFA, for each M+C plan it intends to offer in the following year: (1) The information specified in paragraph (b), (c), or paragraph (d) of this section for the type of M+C plan involved, and (2) The enrollment capacity (if any) in relation to the M+C plan and area.

This collection effort will require the submission of benefit and pricing forms that will be used to price the benefit package sold and describe the benefit package being priced to Medicare beneficiaries. Both collection efforts will be completed at the same time, in order to approve both the benefit and pricing structure of a particular benefit package.

Organizations submitting benefit and pricing forms would include all M+C organizations plus any organization intending to contract with HCFA as a M+C organization.

The estimate of the hour burden of this collection of information is as follows:

Pricing portion of the Adjusted Community Rate Proposal; 1 response per year per respondent × 450 (350 current/100 new) annual respondents × 100 hours of estimated burden per response = 45,000 total annual burden hours.

The Plan Benefit Package portion of the Adjusted Community Rate Proposal; 1 response per year per respondent × 450 (350 current/100 new) annual respondents × 20 hours of estimated burden per response = 9,000 total annual burden hours.

Requirement for Additional Benefits (§ 422.312)

An M+C organization's request to make a withdrawal from the stabilization fund established for an M+C plan to be used during a contract period must be made in writing when the M+C organization notifies HCFA under § 422.306 of its proposed premiums, other cost-sharing amounts, and related information in preparation for its next contract period.

The burden associated with this requirement is captured above in § 422.306.

State Licensure Requirement (§ 422.400)

Except in the case of a PSO granted a waiver under Subpart H of part 422, each M+C organization must: (1) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in § 422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more M+C plans; (2) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an M+C organization; and (3) Demonstrate to HCFA that—(i) The scope of its license or authority allows the organization to offer the type of M+C plan or plans that it intends to offer in the State; and (ii) If applicable, it has obtained the State certification required under § 422.400(b).

The regulations at § 422.400 require health plans to demonstrate to HCFA that they meet the State licensure requirement of section 1855(a)(1) of the Social Security Act. As explained in the preamble, organizations must meet both the basic requirement of State licensure as a risk-bearing entity, as well as the requirement that the scope of licensure be consistent with the type (or types) of M+C plan(s) the organization will be offering. We are asking new organizations (i.e., other than current contractors) to submit, as part of the process of applying for an M+C contract, a written certification showing the organization's licensure status. As of the date of publication of this interim final regulation, we are working with the National Association of Insurance Commissioners to develop a form that may be used to satisfy this requirement. A written statement containing the same type of information that is requested in the form we are developing would also suffice to show compliance with the statutory requirement.

The written certification is a combination of information provided by the organization proposing to enter into an M+C contract, and information to be provided by the appropriate State regulatory body (e.g. the State department of insurance). This is necessary because the written certification serves two purposes. First, it provides us with written evidence of compliance with the State licensure requirement for all M+C plans an organization may wish to offer. Second, it serves to inform State regulators of the intention of organizations doing business within the State with regard to M+C offerings. The certification process enables the State to ensure that the organization is complying with the State's standards for licensure (for example, as noted in the preamble, an HMO that proposes to offer a Medicare point-of-service (POS) product may be informed by the State that HMO licensure does not allow an organization to offer POS products, and that licensure as an indemnity insurer is required in that State in order to offer a POS product).

The certification will have to be completed (or other written

documentation provided) only once by each M+C organization, unless the nature of the M+C plan(s) offered by the organization differ from the original certification (e.g., an HMO may decide at some later date, after its initial application to offer a POS product—though even in such a case, a new certification may not be necessary to the extent that we are aware that applicable State law does not require a different licensure status). We estimate that the time burden for the M+C organization is 10 minutes or less for completion of the certification form, or preparation of alternative written documentation. Similarly, we would estimate, that the time burden for the State regulatory body should be 15 minutes or less (including time necessary to verify information from electronic or paper files).

Because we are estimating that there will be an average of 100 new applicants per year for M+C contracts over the next 5 years, and because this requirement will be imposed for nearly all organizations on a one-time basis, we estimate the annual total burden to be 25 minutes per respondent × 100 annual responses for a total of 42 annual hours.

General Provisions (§ 422.501)/Contract Provisions (§ 422.502)

In order to qualify as an M+C organization, enroll beneficiaries in any M+C plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an M+C organization must enter into a contract with HCFA.

Since the contract requirements associated with these sections are reflective the requirements and associated burden set forth in other sections of Part 422, the remaining burden associated with the requirements of these sections is the time required for a M+C organizations to read and sign the contract. It is estimated that it will take 100 M+C organizations on an annual basis, 2 hours each for a total annual burden of 200 hours. However, we solicit comment on the burden associated with these sections as it relates to the burden of meeting the requirements of the contract as reflected elsewhere in this regulation.

Nonrenewal of Contract (§ 422.506)

An M+C organization that does not intend to renew its contract, must notify HCFA, each Medicare enrollee, and the general public, before the end of the contract. Based on current experience HCFA receives 10 notifications of non-renewal on an annual basis. We estimate that the burden of notifying HCFA is 2 hours per notification for an annual burden of 20 hours.

We estimate the burden associated with notifying enrollees would take 16 hours per plan to draft and disseminate through mass mailings information of changes to affected beneficiaries for an annual burden of 160 hours.

We anticipate notification to the general public would be through the same notice published in a general circulation newspaper and would be an additional burden of 4 hours per organization for an annual burden of 40 hours.

Modification or Termination of Contract by Mutual Consent (§ 422.508)

An M+C organization that modifies or terminates it contract by written mutual consent must notify HCFA, each Medicare enrollee, and the general public, within timeframes specified by HCFA. Based on current experience HCFA receives less then 10 notifications of Modification or termination on an annual basis that would require notification of Medicare enrollees or the general public. However, we estimate that the burden of notifying HCFA is 2 hours per notification for an annual burden of 20 hours.

Termination of Contract by HCFA (§ 411.510)

If HCFA decides to terminate a contract for reasons other than the grounds specified in § 422.510(a)(5), the M+C organization notifies its Medicare enrollees and the general public by publishing a notice in one or more newspapers of general circulation in each community or county located in the M+C organization's geographic area of the termination by mail and at least 30 days before the effective date of the termination. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.4 and 5 CFR 1320.3(c).

Termination of Contract by the M+C Organization (§ 422.512)

The M+C organization may terminate the M+C contract if HCFA fails to substantially carry out the terms of the contract. The M+C organization must give advance notice as follows as required in paragraphs (a)(1) through (a)(3) of § 422.512. In summary, an M+C organization that does not intend to renew its contract, it must notify HCFA, each Medicare enrollee, and the general public, before the end of the contract.

Based upon current experience this requirement is imposed on fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c).

Reporting Requirements (§ 422.516)

Each M+C organization must report to HCFA annually, within 120 days of the end of its fiscal year (unless for good cause shown, HCFA authorizes an extension of time), the requirements in § 422.516 (b)(1) through (b)(3). The burden associate with these requirements is currently captured under form HCFA–906, OMB #0938–0469. Although the burden associated with the completion of the HCFA–906 differs by provider type, on average, the annual burden per provider is 17 annual hours, for a total burden of 3,130 hours. In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

For any employees' health benefits plan that includes an M+C organization in its offerings, the M+C organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations under the Employee Retirement Income Security Act of 1974 (ERISA). The M+C organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term ''administrator'' is defined in ERISA.

These reporting requirements are currently imposed by the Department of Treasury and therefore impose no addition burden.

Each M+C organization must make the information reported to HCFA under § 422.502(f)(1) available to its enrollees upon reasonable request. This burden associated with this requirement is imposed pursuant to the dissemination of enrollment/disenrollment information referenced in Subpart B of this regulation.

Each organization must notify HCFA of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

The burden associate with these requirements is currently captured under form HCFA–906, OMB #0938–0469. In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

Change of Ownership (§ 422.550)

§ 422.550 is amended to require in paragraph (b) that an M+C organization must provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving

organization. The burden associated with these requirements, which is estimated to take 10 hours per respondent × 10 annual respondents, is currently captured under National Data Reporting Requirements, form HCFA–906, OMB #0938–0469. In the near future HCFA will resubmit this collection to OMB for approval for use by M+C organizations.

§ 422.562 General provisions.

An M+C organization, with respect to each M+C plan that it offers, must establish and maintain written procedures related to; (1) the grievance procedures as described in § 422.564, (2) making timely organization determinations, (3) an appeal process that meets the requirements of this Subpart for issues that involve organization determinations.

In addition, an M+C organization must ensure that all enrollees receive written information about the grievance and appeal procedures that are available to them through the M+C organization and complaint process available to the enrollee under the PRO process as set forth under section 1154(a)(14) of the Act.

While we believe the initial burden associated with meeting these requirements is captured elsewhere in this regulation, we solicit comment on the ongoing burden associated with maintaining and disseminating the information requirements set forth in this section.

Standard Timeframes and Notice Requirements for Organization Determinations (§ 422.568)

When a party has made a request for a service, the M+C organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the organization receives the request for a standard organization determination.

If an M+C organization decides to deny service or payment in whole or in part, it must give the enrollee written notice of the determination.

The burden associated with this requirement is discussed below in § 422.572.

Expediting Certain Organization Determinations (§ 422.570)

To ask for an expedited determination, an enrollee or a health care professional must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the determination, as directed by the M+C organization. A physician may provide oral or written support for a request for an expedited determination.

If an M+C organization denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and follow up, within 2 working days, with a written letter that: (1) Explains that the M+C organization will process the request using the 30-calendar-day timeframe for standard determinations, (2) informs the enrollee of the right to file a grievance if he or she disagrees with the M+C organization's decision not to expedite; and (3) provides instructions about the grievance process and its timeframes.

If an M+C organization grants a request for expedited determination, it must make the determination and give notice in accordance with § 422.572.

The burden associated with this requirement is discussed below in § 422.572.

Timeframes and Notice Requirements for Expedited Organization Determinations (§ 422.572)

Except as provided in paragraph (b) of § 422.572, an M+C organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician as warranted by the patient's medical condition or situation) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but not later than 72 hours after receiving the request.

The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization finds that it needs additional information and the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination before or immediately upon expiration of the extension.

If the M+C organization first notifies an enrollee of its expedited determination orally, it must mail written confirmation to the enrollee within 2 working days of the oral notification.

Organizations that contract with HCFA under the M+C program are required to implement procedures for making timely organization determinations and for resolving reconsiderations and other levels of appeals with respect to these determinations. In general, organization determinations involve whether an enrollee is entitled to receive a health service or the amount the enrollee is expected to pay for that service. A reconsideration consists of a review of an adverse organization determination (a decision by an M+C organization that is unfavorable to the M+C enrollee, in whole or in part) by either the M+C organization itself or an independent review entity. We use the term ''appeal'' to denote any of the procedures that deal with the review of organization determinations, including reconsiderations, hearings before administrative law judges (ALJs), reviews by the Departmental Appeals Board (DAB) and judicial review. As discussed in detail in section II.M of this preamble, the organization determination and appeal requirements for M+C organizations that are set forth in this interim final rule are largely based on the existing rules for managed care organizations under Part 417, Subpart Q, Beneficiary Appeals.

Sections 422.568, 422.570, and 422.572 contain the applicable requirements for initial organization determinations, which include submission of an oral or written request from an enrollee, and notification procedures that the M+C organization must follow when it makes a determination. We estimate that approximately 20 percent of the approximately 1 million M+C enrollees may make a request for an organization determination in a year, with an estimated burden of 2 minutes per request. Estimated notification burden associated with these requests is 5 minutes per request. The total overall annual burden for enrollee requests and organizational notification burden is 33,333 hours and 83,333 hours respectively.

Request for a Standard Reconsideration (§ 422.582)

A party to an organization determination must ask for a reconsideration of the determination by filing a written request with: (1) The M+C organization that made the organization determination; (2) an SSA office; or (3) in the case of a qualified railroad retirement beneficiary, an RRB office.

If the 60-day period in which to file a request for a reconsideration has expired, a party to the organization determination may file a request for reconsideration with the M+C organization, SSA, or an RRB office. If SSA or RRB receives a request, it forwards the request to the M+C organization for its reconsideration. The request for reconsideration and to extend the timeframe must: (1) Be in writing; and(2) state why the request for reconsideration was not filed on time.

The party who files a request for reconsideration may withdraw it by filing a written request for withdrawal at one of the places listed in paragraph (a) of this section.

The burden associated with this requirement is discussed below in § 422.602.

Expediting Certain Reconsiderations (§ 422.584)

To ask for an expedited reconsideration, an enrollee or a health care professional (on behalf of an enrollee) must submit an oral or written request directly to the M+C organization or, if applicable, to the entity responsible for making the reconsideration, as directed by the M+C organization. A physician may provide oral or written support for a request for an expedited reconsideration.

If an M+C organization denies a request for expedited reconsideration, it must take the following actions: (1) Automatically transfer a request to the standard timeframe and make the determination within the 45-day timeframe established in § 422.590(a); (2) give the enrollee prompt oral notice, and follow up, within 2 working days, with a written letter that—(i) Explains that the M+C organization will process the enrollee's request using the 45-day timeframe for standard reconsiderations, (ii) informs the enrollee of the right to file a grievance if he or she disagrees with the organization's decision not to expedite, and (iii) provides instructions about the grievance process and its timeframes.

If an M+C organization grants a request for expedited reconsideration, it must conduct the reconsideration and give notice in accordance with § 422.590(d).

The burden associated with this requirement is discussed below in § 422.602.

Timeframes and Responsibility for Reconsiderations (422.590)

If the M+C organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by HCFA as expeditiously as the enrollee's health condition requires, but no later than 45 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

If the M+C organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by HCFA no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

If the M+C organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a) or paragraph (b) of this section, or to obtain a good cause extension described in paragraph (e) of this section, this failure constitutes an affirmation of its adverse organization determination, and the M+C organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2) and (b)(2) of this section.

The M+C organization may extend the 72-hour deadline by up to 14 calendar days if the enrollee requests the extension or if the organization finds that it needs additional information and the delay is in the interest of the enrollee (for example, the receipt of additional medical evidence may change an M+C organization's decision to deny). The M+C organization must notify the enrollee of its determination before or immediately upon expiration of the extension.

If the M+C organization first notifies an enrollee orally of a completely favorable expedited reconsideration, it must mail written confirmation to the enrollee within 2 working days.

If, as a result of its reconsideration, the M+C organization affirms, in whole or in part, its adverse expedited organization determination, the M+C organization must submit a written explanation and the case file to the independent entity contracted by HCFA within 24 hours. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

If the M+C organization refers the matter to the independent entity as described under this section, it must concurrently notify the enrollee of that action.

If the M+C organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (d) of this section, this failure constitutes an adverse reconsidered determination, and the M+C organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (d) of this section.

The burden associated with this requirement is discussed below in § 422.602.

Notice of Reconsidered Determination by the Independent Entity (§ 422.594)

When the independent entity makes the reconsidered determination, it is responsible for mailing a notice of its reconsidered determination to the parties and for sending a copy to HCFA.

See discussion below.

Request for an ALJ Hearing (§ 422.602)

A party must file a written request for a hearing at one of the places listed in § 422.582(a) or with the independent, outside entity. The organizations listed in § 422.582(a) forward the request to the independent, outside entity, which is responsible for transferring the case to the appropriate ALJ hearing office.

Sections 422.582, 422.584, and 422.590 contain the applicable requirements for reconsiderations by an M+C organization of adverse organization determinations. The required procedures generally involve a written request from an enrollee, preparation of a brief written explanation and case file by the M+C organization, and notification of the decision by the M+C organization. Only about 0.5 percent of organization determinations, [that is, about 20,000 cases per year], ever reach the reconsideration stage. For these cases, we estimate a burden on the requesting enrollee of approximately 20 minutes per case and a burden on the M+C organization of approximately 4 hours, including both information collection and notification. Note that § 422.590 specifies that if an M+C organization affirms, in whole or in part, its adverse organization determination, it must forward the case to an independent entity contracted by HCFA for further review. We estimate that approximately 50 percent (10,000) of reconsidered cases result in a decision that is adverse to the enrollee, and thus review by the independent entity. For these cases, we estimate an additional burden on the M+C organization of approximately 2 hours per case. Thus, the estimated total annual burden on M+C organizations associated with reconsiderations is 100,000 hours (4 hours times 20,000 cases plus 2 hours times 10,000 cases).

About 30 percent of reconsideration requests that reach the independent entity level are resolved fully in favor of the enrollee. For the other 7,000 cases, an enrollee may pursue additional appeals, beginning with an appeal to an ALJ. Only about 10 percent of these cases are appealed to the ALJ, and for these 700 cases, we estimate an

incremental burden of 20 minutes on the enrollee to make the request for an appeal under § 422.602, and 2 hours on the M+C organization for additional information collection associated with the appeal. Finally, under §§ 422.608 and 422.612, enrollees or M+C organizations may appeal ALJ decisions to the Departmental Appeal Board, and subsequently request judicial review. We would estimate an incremental burden of an additional 2 to 4 hours per case, with only about 20 DAB cases and 10 judicial review cases per year.

How M+C Organizations Must Notify Enrollees of Noncoverage of Inpatient Hospital Care (§ 422.620)

The M+C organization must give the enrollee written notice that includes the following: (1) The reason why inpatient hospital care is no longer needed, (2) the effective date of the enrollee's liability for continued inpatient care, and (3) the enrollee's appeal rights. If the M+C organization allows the hospital to determine whether inpatient care is necessary, the hospital obtains the concurrence of the contracting physician responsible for the enrollee's hospital care or of another physician as authorized by the M+C organization, and notifies the enrollee, following the procedures set forth in § 412.42(c)(3) of this chapter.

The burden associated with this requirement is discussed below in § 422.622.

Requesting Immediate PRO Review of Noncoverage of Inpatient Hospital Care (§ 422.622)

For the immediate PRO review process, the enrollee must submit the request for immediate review in writing or by telephone to the PRO that has an agreement with the hospital under § 466.78 of this chapter by noon of the first working day after he or she receives written notice that the M+C organization or hospital has determined that the hospital stay is no longer necessary.

Under § 422.620, an M+C organization is required to provide an M+C enrollee, before a hospital discharge, with a written notice of noncoverage if it decides that inpatient care is no longer necessary. Section 422.622 provides the procedures that are to be followed if an enrollee by the enrollee and the M+C organization if the enrollee wishes to request PRO review of the M+C organization's decision. We estimate that there will be no more than 1,000 of these type of cases per year under the M+C program. We estimate that the reporting burden for an M+C organization to provide written notice of noncoverage to be approximately 10 minutes per notice; for an M+C enrollee to complete a request for immediate PRO review to be approximately 10 minutes per request; and for the M+C organization to submit requested medical information to the PRO, to be approximately 2 hours per response.

In response to a request from the M+C organization, the hospital must submit medical records and other pertinent information to the PRO by close of business of the first full working day immediately following the day the organization makes its request.

Given that this requirement is imposed pursuant to an administrative action against an organization, this requirement is not subject to the PRA as defined in 5 CFR 1320.4.

Request for Reconsideration (§ 422.650)

A request for reconsideration must be made in writing and filed with any HCFA office within 15 days from the date of the notice of the initial determination. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

The M+C organization or M+C contract applicant who filed the request for a reconsideration may withdraw it at any time before the notice of the reconsidered determination is mailed. The request for withdrawal must be in writing and filed with HCFA. Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Request for Hearing (§ 422.662)

A request for a hearing must be made in writing and filed by an authorized official of the applicant entity or M+C organization that was the party to the determination under appeal. The request for a hearing must be filed with any HCFA office within 15 days after the date of receipt of the notice of initial or reconsidered determination.

Based upon current experience this requirement is imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Disqualification of Hearing Officer (§ 422.668)

A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to HCFA.

Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Time and Place of Hearing (§ 422.670)

The hearing officer fixes a time and place for the hearing, which is not to exceed 30 days from the receipt of the request for the hearing, and sends written notice to the parties. The notice also informs the parties of the general and specific issues to be resolved and information about the hearing procedure.

Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Record of Hearing (§ 422.686)

A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Notice and Effect of Hearing Decision (§ 422.690)

As soon as practical after the close of the hearing, the hearing officer issues a written decision that: (1) Is based upon the evidence of record, and (2) contains separately numbered findings of fact and conclusions of law. And, the hearing officer provides a copy of the hearing decision to each party. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are

not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

Effect of Revised Determination (§ 422.698)

The revision of an initial or reconsidered determination is binding unless a party files a written request for hearing of the revised determination in accordance with § 422.662. Based upon current experience these requirements are imposed pursuant to an administrative action against fewer than 10 organizations on an annual basis. Therefore, these requirements are not subject to the PRA as defined in 5 CFR 1320.3(c) and 5 CFR 1320.4.

As a note, the public will be afforded several subsequent comment periods in future publications of **Federal Register** notices announcing our intention to seek OMB approval of standardized information collection requirements such as the ACR and contractor application forms that will be submitted to OMB in the near future.

We have submitted a copy of this rule to OMB for its review of the information collection requirements above. To obtain copies of the supporting statement for these collection requirements and any currently approved forms that are related to the proposed paperwork collections referenced above, E-mail your request, including your address, phone number and HCFA regulation identifier HCFA–1011, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

As noted above, comments on these information collection and record keeping requirements must be mailed and/or faxed to the designee referenced below, within ten working days of publication of this collection in the **Federal Register**:

Health Care Financing Administration, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke HCFA–1030, Fax Number: (410) 786–1415

And

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer, Fax Number: (202) 395–6974 or (202) 395–5167

VII. Responses to Comments

Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to them individually. We will, however, consider all comments that we receive by the date specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in that document.

VIII. Waiver of Proposed Rulemaking and Waiver of Delayed Effective Date

Because the Secretary is exercising discretion in implementing sections 1851 through 1857 and section 1859 of the Act, ordinarily we would publish a notice of proposed rulemaking and afford a period for public comments. Further, we generally provide for final rules to be effective no sooner than 30 days after the date of publication unless we find good cause to waive the delay. However, section 1856(b)(1) of the Act requires that these regulations be published by June 1, 1998, and provides that in order to carry out this requirement we may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

On January 20, 1998, we published a notice in the **Federal Register** in which we requested public comments on the implementation of the M+C program. We received approximately 90 items of correspondence in response to that notice. Further, on February 4, 1998, we held a public meeting to discuss issues and concerns from plans, providers, beneficiaries, and other interested parties on the requirements and implementation of the Medicare+Choice program. Approximately 600 individuals representing managed care organizations, local governmental agencies, and advocacy groups attended that meeting.

Because of the need to publish regulations timely and in light of the fact that we previously provided opportunity for public comment, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 90-day comment period for public comment. We also find good cause to waive the delay in the effective date of this rule.

IX. Effect of the Contract With America Advancement Act of 1996 (Public Law 104–121)

This rule has been determined to be a major rule as defined in Title 5, United States Code, section 804(2). Ordinarily under 5 U.S.C. 801, as added by section 251 of Public Law 104–121, a major rule shall take effect 60 days after the later of (1) the date a report on the rule is submitted to the Congress, or (2) the date the rule is published in the **Federal Register**. However, section 808(2) of Title 5, United States Code, provides that, notwithstanding 5 U.S.C. 801, a major rule shall take effect at such time as the Federal agency determines if for good cause the agency finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. As explained above, for good cause we find that it was impracticable, unnecessary, or contrary to the public interest to complete notice and comment procedures before publication of this rule. Accordingly, pursuant to 5 U.S.C. 808(2), these regulations are effective on July 27, 1998.

BILLING CODE 4120–01–P

42 CFR Chapter IV is amended as set forth below.

A. Part 400

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation for part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. chapter 35.

2. In § 400.200, the definition for ''PRO'' is revised and the following definitions are added in alphabetical order to read as follows.

§ 400.200 General definitions.

* * * * *

ALJ stands for administrative law judge.

* * * * *

NCD stands for national coverage determination.

* * * * *

Peer review organization means an organization that has a contract with HCFA, under part B of title XI of the Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

PRO stands for peer review organization.

* * * * *

RRB stands for Railroad Retirement Board.

* * * * *

3. In § 400.202 a definition of ''national coverage determination'' is added in alphabetical order to read as follows.

§ 400.202 Definitions specific to Medicare.

* * * * *

National coverage determination (NCD) means a national policy determination regarding the coverage status of a particular service, that HCFA

makes under section 1862(a)(1) of the Act, and publishes as a **Federal Register** notice or HCFA Ruling. (The term does not include coverage changes mandated by statute.)

* * * * *

B. Part 403

PART 403—SPECIAL PROGRAMS AND PROJECTS

1. The authority citation for part 403 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 403.205, paragraph (d) introductory text is revised to read as follows:

§ 403.205 Medicare supplemental policy.

* * * * *

(d) Medicare supplemental policy does not include a Medicare+Choice plan or any of the following health insurance policies or health benefit plans:

* * * * *

C. Part 410

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Part 410 is amended as set forth below.

a. Section 410.57 is revised to read as follows:

§ 410.57 Pneumococcal vaccine and flu vaccine.

(a) Medicare Part B pays for pneumococcal vaccine and its administration when reasonable and necessary for the prevention of disease, if the vaccine is ordered by a doctor of medicine or osteopathy.

(b) Medicare Part B pays for the influenza virus vaccine and its administration.

b. Section 410.152 is amended to add a paragraph (1) to read as follows:

§ 410.152 Amounts of Payment.

* * * * *

(1) *Amount of payment: Flu vaccine.* Medicare Part B pays 100 percent of the Medicare allowed charge.

D. Part 411

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 411.15 [Amended]

2. In § 411.15, in paragraph (e), the following changes are made:

a. The ''and'' at the end of paragraph (e)(2) is removed.

b. A semicolon and the word ''and'' are added at the end of paragraph (e)(3).

c. A new paragraph (e)(4) is added, to read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(e) * * *

(4) Influenza vaccinations that are reasonable and necessary for the prevention of illness.

* * * * *

3. In § 411.355, a new paragraph (c)(5) is added, to read as follows:

§ 411.355 General exceptions to referral prohibitions related to both ownership/investment and compensation.

* * * * *

(c) * * *

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with HCFA under section 1857 of the Act and part 422 of this chapter.

* * * * *

E. Part 417

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9); and 31 U.S.C. 9701.

2. Section 417.402 is revised to read as follows:

§ 417.402 Effective date of initial regulations.

(a) The changes made to section 1876 of the Act by section 114 of the Tax Equity and Fiscal Responsibility Act of 1982 became effective on February 1, 1985, the effective date of the initial implementing regulations.

(b) The changes made to section 1876 of the Act by section 4002 of the Balanced Budget Act (BBA) of 1997 are incorporated in section 422 except for 1876 cost contracts. Upon enactment of the BBA (August 5, 1997) no new cost contracts or service area expansions are accepted by HCFA except for current Health Care Prepayment Plans that may convert to 1876 cost contracts. Also, 1876 cost contracts may not be extended or renewed beyond December 31, 2002.

3. In § 417.413, paragraphs (d)(1) and (d)(2) introductory text are revised and new paragraphs (d)(2) (iii) and (d)(8) are added to read as follows:

§ 417.413 Qualifying condition: Operating experience and enrollment.

* * * * *

(d) *Standard: Composition of enrollment.* (1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an HMO's or CMP's enrollment may be Medicare beneficiaries.

(2) *Waiver of composition of enrollment standard.* HCFA may waive compliance with the requirements of paragraph (d)(1) of this section if the HMO or CMP has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries and it meets one of the following requirements:

* * * * *

(iii) The HMO or CMP requests waiver of the composition rule because it is in the public interest. The organization provides documentation that supports one of the following:

(A) The organization serves a medically underserved rural or urban area.

(B) The organization demonstrates a long-term business and community service commitment to the area.

(C) The organization believes that a waiver is necessary to promote managed care choices in an area with limited or no managed care choices.

* * * * *

(8) *Termination of composition standard.* The 50 percent composition of Medicare beneficiaries terminates for all managed care plans on December 31, 1998.

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4. In § 417.426, a new paragraph (a)(4) is added to read as follows:

§ 417.426 Open enrollment requirements.

(a) *Basic requirements.* * * *

(4) An HMO or CMP with a risk contract must accept applications from eligible Medicare beneficiaries during the month of November 1998.

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5. Section 417.428 is revised to read as follows: